

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152525	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 08/07/2015
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 1225 W 86TH ST INDIANAPOLIS, IN 46260
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V 0000 Bldg. 00	<p>This was a Federal ESRD [CORE] recertification survey.</p> <p>Survey Dates: 8-3-15, 8-4-15, 8-5-15, 8-6-15, and 8-7-15</p> <p>Facility #: 005139</p> <p>Medicaid Vendor #: 100217180A</p> <p>FMC Indianapolis North was found to be out of compliance with Conditions for Coverage 42 CFR 494.90 Plan of Care, 42 CFR 494.494.100 Care At Home, and 42 CFR 494.150 Responsibilities of the Medical Director.</p> <p>QA; LD, R.N.</p>	V 0000		
V 0113 Bldg. 00	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure hand hygiene and glove changes had been performed in accordance with facility policy in 5 (#s 7,9, 10, 13, 14, and 15) of 15 hand</p>	V 0113	The Director of Operations for In-center is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of	09/16/2015

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>hygiene observations completed.</p> <p>The findings include:</p> <ol style="list-style-type: none"> Employee H, a patient care technician (PCT), was observed to initiate the dialysis treatment on patient number 14 on 8-4-15 at 10:00 AM using an arteriovenous fistula (AVF). The PCT was observed to evaluate the access using palpitation and a stethoscope. The PCT was not observed to change her gloves and cleanse her hands after evaluating the access and prior to cleansing the skin over the access site in preparation for inserting the needles. Employee P, a PCT, was observed to discontinue the dialysis treatment on patient number 15 on 8-4-15 at 10:40 AM using an AVF. The PCT was observed to reinfuse the extracorporeal circuit. The PCT was not observed to change her gloves or cleanse her hands prior to removing the needles and applying gauze to the needle insertions sites. Employee P, a PCT, was observed to discontinue the dialysis treatment on patient number 16 on 8-4-15 at 12:00 PM. The PCT was observed to reinfuse the extracorporeal circuit. The PCT was not observed to change her gloves or 		<p>action plans. The QAI Committee is responsible to provide oversight until ongoing resolution has been determined. The Clinical Manager is responsible to ensure that all staff members follow "Hand Hygiene" and "Infection Control Overview" policies to ensure a safe treatment environment that prevents cross contamination of patients and equipment. The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members on the following policies: "Hand Hygiene" FMS-CS-IC-II-105-032C and Infection Control Overview Policy FMS-CS-IC-II-155-060A with emphasis placed on appropriate glove changes and hand hygiene when providing care to the dialysis patient. The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members on the following policies. The Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done daily for 2 weeks, weekly for 4 weeks, monthly 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</p>	

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	<p>cleanse her hands prior to removing the needles and applying gauze to the needle insertions sites.</p> <p>4. Employee F, a registered nurse (RN), was observed to administer intravenous Epogen and Venofer to patient number 17 on 8-4-15 at 11:50 AM. The RN prepared the medications and took them to the dialysis station. The RN was observed to touch the keyboard to check the dosages on the computer at the chairside. The RN was not observed to cleanse her hands prior to donning clean gloves and administering the medication to the patient.</p> <p>5. Employee E, an RN, was observed to administer intravenous Epogen and Venofer to patient number 18 on 8-4-15 at 12:40 PM. The RN prepared the medications and took them to the dialysis station. The RN was observed to touch the keyboard to check the dosages on the computer at the chairside. The RN was not observed to cleanse her hands prior to donning clean gloves and administering the medication to the patient.</p> <p>6. Employee AA, an RN, was observed to obtain a blood sample from patient number 8, a peritoneal dialysis patient, on 8-5-15 at 2:20 PM. The RN was observed to cleanse her hands and don</p>		<p>corrective actions appropriate</p> <p>The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to provide oversight until ongoing resolution has been determined. The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p> <p>Home Therapy Response to v113</p> <p>The Director of Operation has reviewed the following policies with the Home Program Manager on 9/14/15 and emphasized his responsibility to ensure that all direct patient care staff follow Policy and Procedure.</p> <ul style="list-style-type: none"> · Initiation of a Peripheral IV Policy (FMS-CS HT-I-205-005C) · Hand Hygiene Policy (FMS-CS-IC-II-155-090C) <p>The Clinical Manager will hold a staff meeting on 9/15/2015 to review the above policy with the specific area of focus being related to the Hand Hygiene, glove usage and application of tourniquet. Effective 9/15/2015, the Home Program Manager or his designee will complete weekly infection</p>		

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	<p>clean gloves and obtain the needed supplies from a drawer. The RN then applied a tourniquet to the patient's right arm. Without changing her gloves or cleansing her hands, the RN cleansed the right antecubital area. After cleansing the site, the RN touched the site with her gloved finger and inserted the needle.</p> <p>6. The clinic manager, employee A, indicated, on 8-4-15 at 4:15 PM, the employees had not provided care in accordance with the facility's infection control policies and procedures.</p> <p>7. 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)."</p> <p>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.</p>		<p>control monitoring utilizing "clinic audit checklist" focusing on hand hygiene and proper use of gloves. This audit will continue until 100% compliance is obtained by all staff. Issues of noncompliance will be addressed immediately to include performance improvement plans or corrective action as needed. The weekly monitoring results will be presented by the Home Program Manager at the monthly QAI meeting for analysis, trending and discussion. If, after 4 weeks of monitoring, the results show 100% compliance is met, the monitoring will be reduced to a monthly basis; then the QAI team will review the results at each meeting and at that time will be responsible for determining the frequency of the audits utilizing the Infection Control Audit Tools per the QAI calendar schedule. The Home Program Manager is responsible to evaluate and present the "clinic audit checklist" findings in the monthly QAI meeting. The QAI Committee is responsible to review, analyze and trend all monitoring results to ensure resolution is both occurring and is sustained The Director of Operations is responsible to ensure that the</p>	

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	<p>IV.A.3.b. After contact with blood, body fluids or excretions, mucous membranes, nonintact skin, or wound dressings.</p> <p>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).</p> <p>IV.3.d. If hands will be moving from a contaminated-body site to a clean-body site during patient care.</p> <p>IV.A.3.e. After contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient.</p> <p>IV.A.3.f. After removing gloves . . .</p> <p>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 . . .</p> <p>IV.B. Personal protective equipment (PPE) . . .</p> <p>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."</p>		<p>data required within this Plan of Correction is presented to the QAI Committee on a monthly basis for evaluation.</p> <p>The Director of Operations has reviewed the following policies with the Home Program manager on 9/14/2015 and emphasized his responsibility to ensure that all direct patient care staff follow Policy and Procedure. On September 15th, 2015, the Home Program Manager reviewed the "comprehensive Interdisciplinary Assessment and Plan of Care" policy with the Dietitian, Social Worker and Nursing Staff in reference to "provide the necessary care and services to maintain the patients' hemoglobin of greater than 10 grams per deciliter (g/dl). The Home Program Manager will audit 100% of all patients' hemoglobin and iron levels by 9/18/2015 to ensure hemoglobin and iron levels are within the appropriate physician ordered target range. On 8/9/2015 the Home Clinical Manager began auditing 100% of medication administration for all epogen and venofer administration for documentation and accuracy. The Home Program Manager will ensure compliance by auditing the medical records in</p>				

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V 0122 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-]		accordance with QAI Medical Record Auditing requirements, using the Medical Record audit tool on a monthly basis. Specifically during the medical record audits, labs results and medication administration will be reviewed and records found incomplete, not appropriate or lacking documentation of accurate medication administration will be immediately addressed and corrected. The Home Program Manager is responsible to analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review. The Director of Operations is responsible to ensure that the data required within this Plan of Correction is presented to the QAI Committee on a monthly basis for evaluation.		

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	<p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure dialysis stations had been cleaned and disinfected in accordance with facility policy in 2 (#s 1 and 2) of 2 cleaning and disinfection of the dialysis station observations completed.</p> <p>The findings include:</p> <p>1. Employee N, a patient care technician (PCT), was observed to clean and disinfect the dialysis machine and chair at station number 7 on 8-4-15 at 10:25 AM. The PCT was not observed to clean the sides of the dialysis machine, the Hansen connectors, or the dialysate hoses. The PCT was observed to clean the front of the machine then empty the prime waste bucket. The employee was not observed to clean the inside or the back of the bucket prior to replacing it onto the machine.</p> <p>The PCT was not observed to clean the outside of the sides of the chair or the fronts of the arms of the chairs where patients place their hands. The PCT was not observed to clean the TV or the data entry station.</p>	V 0122	<p>On September 11th 2015 the Governing Body met to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution. The Clinical Manager is responsible to ensure that all staff members follow these policies</p> <p>FMS-CS-IC-II-155-110A "Cleaning and Disinfection" and "Priming Bucket Disinfection Procedure</p> <p>FMS-CS-IC-1-105-007C with emphasis placed on cleaning the dialysis station and prime buckets. The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members on these policies. Training will be complete by September 15th 2015. A staff in-service sheet and attendance sheet is available within the facility. The Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done daily for 2 weeks, weekly for 4 weeks, monthly 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</p>	09/16/2015			

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	<p>2. Employee G, a PCT, was observed to clean and disinfect the dialysis machine and chair at station number 1 on 8-4-15 at 3:55 PM. The PCT clean the intravenous pole, the crit line monitor, and the blood pressure cuff. The PCT then empties the prime waste container and cleaned it. The PCT used the same cloth to then complete the cleaning of the machine. The PCT was not observed to clean the side of the machine under the prime waste bucket or the dialysate hoses.</p> <p>Employee R, a PCT, was observed to clean the chair at station number 1 on 8-4-15 at 3:25 PM. The PCT was not observed to clean the outside of the chair or the fronts of the arms of the chair where patients place their hands. The PCT was not observed to clean the TV or the data entry stations.</p> <p>3. The clinic manager, employee A, indicated, on 8-4-15 at 4:15 PM, employees G, N, and R had not cleaned and disinfected the dialysis machine and chair in accordance with the facility's policies and procedures.</p> <p>4. 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</p>		<p>action as appropriate. The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to provide oversight until ongoing resolution has been determined.</p>	

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V 0147 Bldg. 00	<p>after completion of procedures . . .</p> <p>Externally disinfect the dialysis machine with 1:100 bleach solutions after each dialysis treatment. Non-disposable items such as blood pressure cuffs, IV poles, TVs, TV remotes, portable phones, etc., as well as clip boards or plastic hemostat clamps placed on the machine used or unused, should be disinfected with 1:100 bleach solution after each treatment.</p> <p>5. The facility's 4-4-12 "Priming Bucket Disinfection" procedure number FMS-CS-IC-I-105-007C states, "Clean all surfaces of the priming bucket or approved receptacle, with a wipe that has been wetted with 1:100 bleach solution as per facility surface disinfection procedures. Return clean priming bucket or approved receptacle to the machine."</p> <p>494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to</p>			

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	<p>guidelines periodically for all persons who manage intravascular catheters.</p> <p>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.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>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 review of facility policy, the facility failed to ensure central venous catheter (CVC) care had been completed in accordance with facility policy in 4 (#s 1, 2, 5, and 6) of 6 CVC observations completed.</p> <p>The findings include:</p> <p>1. Employee G, a patient care technician (PCT), was observed to initiate the dialysis treatment on patient number 11 on 8-3-15 at 3:00 PM using a CVC. The PCT was observed to remove the caps from the arterial and venous limbs. The PCT was observed to clean the venous</p>	V 0147	<p>On September 11th 2015 the Governing Body met to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members on the following policies "Hand Hygiene" FMS-CS-IC-II-155-090A," Initialtion of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" FMS-CS-IC-I-105-002C and " Termination of Treatment</p>	09/16/2015

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	<p>hub with an alcohol pad for only 2 seconds and the arterial hub for only 3 seconds.</p> <p>2. Employee G, a PCT, was observed to initiate the dialysis treatment on patient number 12 on 8-3-15 at 4:50 PM using a CVC. The PCT was observed to remove the caps from the arterial and venous limbs. The PCT was observed to clean the venous hub with an alcohol pad for only 10 seconds and the arterial hub for only 8 seconds.</p> <p>3. Employee Q, a PCT, was observed to discontinue the dialysis treatment on patient number 1 on 8-3-15 at 3:10 PM.</p> <p>A. The PCT was not observed to place a clean field under the CVC ports prior to starting the discontinuation procedure.</p> <p>B. The PCT was observed to disconnect the blood lines from the CVC limbs. The PCT was observed to clean the venous open hub with an alcohol pad for only 10 seconds before placing a sterile cap on the hub.</p> <p>4. Employee G, a PCT, was observed to discontinue the dialysis treatment on patient number 13 on 8-3-15 at 4:00 PM.</p>		<p>Using a Central Venous Catheter and Optifluc Single Use Ebeam Dialyzer" FMS-CS-IC-I-105-028C with emphasis placed on placing a clean field under the CVC ports prior to initiating and discontinuation of treatment as well as ensuring the dialysis hubs are cleaned for a minimum of 15 seconds before initiation and discontinuation of treatment reported. Training will be completed by September 15th 2015 and an in-service attendance sheet is available in the facility for review The Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done daily for 2 weeks, weekly for 4 weeks, monthly via 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 Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to provide oversight until ongoing resolution has been determined The Clinical Manager is responsible to report</p>				

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	<p>A. The PCT was not observed to place a clean field under the CVC ports prior to starting the discontinuation procedure.</p> <p>B. The PCT was observed to disconnect the blood lines from both the arterial and venous catheter limbs. The PCT was observed to clean the arterial hub for only 3 seconds and the venous hub for only 4 seconds before placing sterile caps on the hubs.</p> <p>5. The clinic manager, employee A, indicated, on 8-4-15 at 4:15 PM, employees G and Q had not provided CVC care in accordance with facility policies and procedures.</p> <p>6. The facility's 1-6-14 "Initiation of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" procedure number FMS-CS-IC-I-105-002C states, "Remove cap from clamped arterial limb . . . Using a new sterile alcohol pad, scrub threads of the luer lock (hub) vigorously, using back and forth friction for 15 seconds-let dry and discard pad . . . Repeat steps 3 through 5 for the venous end of the catheter limb."</p> <p>7. The facility's 1-6-14 "Termination of Treatment Using a Central Venous</p>		a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.	

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V 0407 Bldg. 00	<p>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 . . . Disconnect the arterial bloodline line from the catheter limb. Using a new sterile alcohol pad, scrub threads of the luer lock (hub) vigorously using back and forth friction for 15 seconds-let dry and discard pad . . . Repeat steps 5 through 8 for the venous end of the catheter limb."</p> <p>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 patients had been monitored at least every 30 minutes during the dialysis treatment per facility policy in 3 (#s 1, 5, and 7) of 7 incenter hemodialysis patient records reviewed.</p> <p>The findings include:</p> <p>1. Clinical record number 1 failed to evidence the patient had been monitored at least every 30 minutes during the dialysis treatment. A hemodialysis</p>	V 0407	<p>On September 11th2015 the Governing Body met to review the statement of deficiencies andto make certain that all identified deficiencies are being addressed bothimmediately and with long term resolution TheClinical Manager is responsible to ensure that all staff members follow policies FMS-CS-IC-I-110-133A "MonitoringDuring Patient Treatment Policy" TheClinical Manager met with the facility Education Coordinator to arrange andschedule staff in-services to re-educate all staff members on the followingpolicy</p>	09/16/2015

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	<p>treatment flow sheet dated 7-20-15 evidenced the patient's blood pressure had been checked at 1:33 PM and not again until 2:32 PM, a period of 59 minutes between checks.</p> <p>The flow sheet evidenced safety and access checks had been completed at 1:36 PM and not again until 2:34 PM, a period of 58 minutes between checks.</p> <p>2. Clinical record number 5 failed to evidence the patient had been monitored at least every 30 minutes during the dialysis treatment.</p> <p>A. A hemodialysis treatment flow sheet dated 7-10-15 evidenced a blood pressure check had been completed at 10:33 AM and not again until 11:21 AM. The flow sheet evidenced access and safety checks had been completed at 10:34 AM and not again until 11:22 AM, a period of 48 minutes between blood pressure and safety checks.</p> <p>B. A hemodialysis treatment flow sheet dated 7-15-15 evidenced a blood pressure check had been completed at 11:12 AM and not again until 12:03 PM, a period of 51 minutes. The flow sheet evidenced access and safety checks had been completed at 11:14 AM and not again until 12:05 PM, a period of 51</p>		<p>FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment Policy with emphasis placed on the requirement of the patient safety checks being completed every 30 minutes during the dialysis treatment. Training will be completed by September 15th 2015 and an in-service attendance sheet is available in the facility for review. The Clinical manager or designee will conduct audits via the QAI Treatment Sheet Audit tool. These audits will be completed daily for 2 weeks, weekly for 4 weeks, monthly via the QAI calendar. The Clinical Manager is responsible to review, analyze and trend all reports and present them monthly to the QAI Committee for review. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to provide oversight until ongoing resolution has been determined. The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p>	

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	<p>minutes between checks.</p> <p>C. A hemodialysis treatment flow sheet dated 7-29-15 evidenced a blood pressure check had been completed at 10:34 AM and not again until 11:34 AM, a period of 60 minutes between checks. The flow sheet evidenced access and safety checks had been completed at 10:38 AM and 11:35 AM, a period 57 minutes between checks.</p> <p>3. Clinical record number 7 failed to evidence the patient had been monitored at least every 30 minutes during the hemodialysis treatment.</p> <p>A. A hemodialysis treatment flow sheet dated 7-15-15 evidenced a blood pressure check had been completed at 3:01 PM and not again until 3:59 PM, a period of 58 minutes between checks. The flow sheet evidenced access and safety checks had been completed at 3:04 PM and not again until 4:00 PM, a period of 56 minutes between checks.</p> <p>B. A hemodialysis treatment flow sheet dated 7-17-15 evidenced a blood pressure check had been completed at 2:30 PM and not again until 3:36 PM, a period of 1 hour and 6 minutes between checks. The flow sheet evidenced access and safety checks had been completed at</p>			

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V 0413 Bldg. 00	<p>2:32 PM and not again until 3:38 PM, a period of 1 hour and 6 minutes between checks.</p> <p>4. The clinic manager, employee A, indicated, on 8-6-15 at 1:30 PM, the facility's policy required the patients to be checked at least every 30 minutes.</p> <p>5. The facility's 8-20-14 "Patient Monitoring During Patient Treatment" policy number FMS-CS-IC-I-110-133A states, "Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary."</p> <p>494.60(d)(3) PE-ER EQUIP ON PREMISES-02, AED, SUCTION Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available. Based on observation, interview, and review of facility policy, the facility failed to ensure the emergency cart in the home program area had been monitored and up-to-date supplies maintained in 1 (#2) of 2 emergency carts observed.</p> <p>The findings include:</p>	V 0413	<p>On September 11th 2015 the Governing Body met to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution. The Clinical Manager is responsible to ensure that staff complete correctly the Emergency Cart Daily Checklist to ensure the cart has</p>	09/16/2015

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	<p>1. On 8-5-15 at 11:30 AM, observation noted an emergency crash cart in the home program area. The cart included 1 package of pediatric electrode pads, used in conjunction with the automated external defibrillator, with an expiration date of 05/2015.</p> <p>The cart failed to evidence an itemized log to track the contents of the cart and expiration dates of the contents.</p> <p>2. The Home Program Director of Operations, employee BB, indicated, on 8-5-15 at 11:30 AM, the emergency cart did not include current pediatric electrode pads. The director indicated the facility currently had 5 pediatric patients on census that made visits to the clinic. The director was unable to provide any additional documentation and/or information when asked about an itemized log for the emergency cart.</p> <p>3. The facility's 1-28-15 "Emergency Medications, Equipment and Supplies" policy number FMS-CS-IC-II-130-007A states, "The emergency supplies must be checked monthly or after use for contents, expiration dates as well as cleanliness and proper functioning of all equipment . . . An itemized log must be kept indicating the contents of the emergency cart/box and expiration dates</p>		<p>up to date supplies . The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to re-educate all staff members on the Emergency Cart Daily Checklist and "Emergency Medications, Equipment and Supplies" FMS-CS-IC-II-130-007A policy and with emphasis placed on checking the expiration dates of all supplies. Training will be completed by September 15th 2015 and an in-service attendance sheet is available in the facility for review. The Clinical Manager will ensure the accuracy of all records by utilizing the QAI Technical audit tools that are done via the QAI calendar which is monthly or 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 review, analyze and trend all reports and present them monthly to the QAI Committee for review. The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI</p>	

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V 0540 Bldg. 00	of contents." 494.90 CFC-PATIENT PLAN OF CARE Based on clinical record and facility policy review, observation, and interview, it was determined the facility failed to maintain compliance with this condition by failing to ensure plans of	V 0540	Committee is responsible to provide oversight until ongoing resolution has been determined TheClinical Manager is responsible to report a summary of findings monthly in QAl and compliance will be monitored by the Governing Body. Home Therapy Response: The Director of Operations for Home Therapies as reviewed the following policy "Emergency Medications, Equipment and Supplies" policy FMS-CS-IC-300-007A on 9/16/2015. The Home Therapy Program Manager implemented Emergency Chart audit tool on 8/10/2015. An itemized log identifying contents of emergency cart and expirations dates. The Home Therapy Program manager will complete monthly audit to ensure all emergency contents are functional and ready to use. The Home Therapy Program manager will present audit results at monthly QAI meeting starting on 9/16/2015. The Governing Body of this facility acknowledges its responsibility to ensure that all patients' Plans of Care are complete and include the participation of all members of the IDT including the patient in the	09/16/2015	

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	<p>care were individualized and specified parameters for the administration of as needed medications in 2 of 10 records reviewed (see V 541); by failing to ensure care and services had been provided to manage patients' blood pressures and volume status in 5 of 10 records reviewed (See V 543); by failing to ensure the prescribed dose of dialysis had been maintained in 2 of 10 records reviewed (See V 544); by failing to ensure the necessary care and services to maintain the patients' hemoglobin of greater than 10 grams per deciliter (g/dL) had been provided in 2 of 6 records reviewed for anemia management (See V 547); and by failing to ensure post dialysis access care had been provided in accordance with facility policy in 1 of 2 discontinuation of dialysis and post dialysis access care observations completed (See V 550).</p> <p>The cumulative effect of these systemic problems resulted in the facility being found out of compliance with this condition, 42 CFR 494.90 Patient Plan of Care.</p>		<p>development and implementation of the Plan; thatthe Plan provides for blood pressure and fluid monitoring, adequacy monitoringto include ordered blood flow rates, ensuring all labs are monitored monthly, postaccess care, medications provided as ordered, and that they are seen by a medical practitionermonthly. The Governing Body reviewed theSOD and determined the immediate corrections required and the following actionsteps were agreed upon and implemented: Effective immediately:</p> <ul style="list-style-type: none"> ·The GoverningBody will meet weekly to review the status of the Plan of Correction specific to this Statement of Deficiencies. ·The ClinicalManager, in conjunction with the Home Program Manager will continue to analyzeand trend all data and monitoring/audit results as related to this Plan ofCorrection focusing on the specifics that were recently identified in theStatement of Deficiency prior to presenting the monthly data to the QAICommittee for oversight and review. ·The Director ofOperations will present an update on the Plan of Correction and all other actionstaken toward the resolution of the deficiencies at each Governing Body meetingthrough to the resolution. ·The processes asnoted in this 	

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			<p>POC will be reviewed by the Governing Body at each meeting. These meetings will ensure ongoing progresstowards resolution of noted deficiencies is being provided.</p> <p>·Minutes of theGoverning Body and QAI meetings, as well as monitoring forms, educationaldocumentation will provide evidence of these actions, the Governing Body'sdirection and monitoring of facility activities. These will be available for review at thefacility.</p> <p>The response provided for V 541 describes, in detail, the processes and monitoringsteps taken to ensure that all members of the interdisciplinary team hadaddressed the blood pressureparameters for the administrationof PRN medication Clonidine HCL 0.1gm</p> <p>The response provided for V 543 describes, in detail, the processes and monitoringsteps taken to ensure that all blood pressure issues are addressed with thephysician. with monthly updates beingdone on the Plan of Care as needed. The response provided for V 544 describes, in detail, the processes and monitoringsteps taken to ensure that all patients' Dose of Dialysis and the prescribeddoes of dialysis is correct to ensure patients meet FMS target</p> <p>The response provided for V 547 describes, in detail, the processes and monitoringsteps taken to</p>	

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V 0541 Bldg. 00	<p>494.90 POC-GOALS=COMMUNITY-BASED STANDARDS</p> <p>The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care were individualized and specified parameters for the administration of as needed medications in 2 (#s 1 and 6) of 10 records reviewed.</p>	V 0541	<p>ensure that all patients' hemoglobin's are at the desired level including interventions to sustain the hemoglobin level and medications are administered as prescribed with monthly updates being done on the Plan of Care.</p> <p>The response provided for V 550 describes, in detail, the processes and monitoring steps taken to ensure that post access care is provided in accordance with our policy and procedure.</p> <p>On September 16th 2015, the Regional Quality Manager met with the members of the IDT to emphasize the requirements as defined within the Conditions of Coverage and Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" that all patients must have a Plan</p>	09/16/2015

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	<p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 1 included physician orders dated 2-2-15 that state, "Treatment Medications . . . Clonidine HCl [hydrochloride] [medication used to lower blood pressure] 0.1 gm [grams] oral prn [as needed]. may repeat X 1." The order failed to evidence blood pressure parameters for the administration of the medication. 2. Clinical record number 6 included physician orders dated 10-13-14 that state, "Treatment Medications . . . Clonidine HCl 0.1 gm oral during dialysis prn-may repeat x1." The order failed to evidence blood pressure parameters for the administration of the medication." 3. Employee DD, the Director of Operations for the incenter unit, indicated, on 8-4-15 at 9:15 AM, the orders did not include any parameters for the administration of the Clonidine. The director stated, "The nurse should call the physician. Most orders say for systolic blood pressure greater than 180." 4. The facility's 7-4-12 "Determination of Blood Pressure" policy number FMS-CS-IC-I-110-134A states, "The Medical Director in conjunction with the 		<p>of Care that is specific to address the patient's needs and is based upon that patient's specific Comprehensive Assessment and that all disciplines must participate in the development. This review specifically included the requirement that blood pressure parameters are individualized to each patient and PRN blood pressure medications require directions on what B/P parameters to use. All patients' Plans of Care will be audited by September 18th 2015 to ensure that all Plans of Care include desired outcomes/goals and estimated timetables to achieve those outcomes/goals, including blood pressures and fluid management individualized to the patient. . Any patient's Plan of Care found to be out of compliance will be presented to the IDT for completion of a POC update by September 21th 2015</p> <p>Ongoing compliance will be monitored through use of the monthly medical record review, using the QAI medical record audit tool and according to the QAI calendar. Any POC's found out of compliance will be scheduled for completion within the next 30 days The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring.</p>	

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V 0543 Bldg. 00	<p>Clinical Manager will determine what the blood pressure upper and lower range parameters will be for the facility. The parameters can also be modified by the nephrologist for individual patients that may required modifications based on their comorbid conditions."</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; Based on clinical record and facility policy review and interview, the facility failed to ensure care and services had been provided to manage patients' blood pressures and volume status in 5 (#s 1, 4, 5, 6, and 7) of 10 records reviewed.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included physician orders dated 2-2-15 that state, "Treatment Medications . . . Clonidine HCl [hydrochloride] [medication used to lower blood pressure] 0.1 gm [grams] oral prn [as needed]. may repeat X 1." The record failed to evidence the Clonidine had been administered as</p>	V 0543	<p>Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.</p> <p>To specifically address inclusion of the patient's volumestatus to manage blood pressures and dry weights in the patient care plan, the following hasoccurred: ·Reeducation of the IDT and attending physicianson policy FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment andPlan of Care on September 16th2015 ·Review of 100% of the patient records by September18thh 2015 ·Any patient found out of compliance will have aplan of care update completed andreviewed at the Plan of Care meeting on September 21st 2015 ·Implement a weekly monitoring process of runningthe</p>	09/16/2015

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	<p>ordered.</p> <p>A. A hemodialysis treatment flow sheet dated 7-16-15 evidenced the patient's blood pressure was 219/97 at 9:48 AM, 215/97 at 10:19 AM, 201/99 at 11:03 AM, and 206/84 at 12:15 PM. The flow sheet evidenced the treatment was completed at 12:16 PM.</p> <p>The record failed to evidence the registered nurse (RN) had notified the physician of the elevated blood pressures or had administered any Clonidine per the physician's orders.</p> <p>B. A hemodialysis treatment flow sheet dated 7-27-15 evidenced the patient's blood pressure was 193/91 at 12:06 PM, 193/81 at 12:31 PM, 184/86 at 1:02 PM, 198/86 at 1:33 PM, and 188/82 at 3:00 PM.</p> <p>The record failed to evidence the registered nurse (RN) had notified the physician of the elevated blood pressures or had administered any Clonidine per the physician's orders.</p> <p>2. Clinical record number 4 included physician orders dated 7-6-15 that state, "Treatment Medications . . . Clonidine HCl 0.1 mg [milligrams] oral during dialysis PRN SBP [systolic blood</p>		<p>hemodialysis treatment report and presenting to the physician any patients with blood pressure ranges out of parameters. The Clinical Manager is responsible to report a summary of findings monthly to the QAI. The QAI Committee is responsible to analyze the results and determine a root cause analysis and new Plan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.</p>	

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	<p>pressure] > [greater than] 180 mmHg [millimeters of mercury]."</p> <p>A. A hemodialysis treatment flow sheet dated 7-27-15 evidenced the patient's blood pressure was 181/99 at 1:02 PM, 191/91 at 1:30 PM, and 187/111 at 2:01 PM. The record failed to evidence any Clonidine had been administered as ordered.</p> <p>B. A hemodialysis treatment flow sheet dated 7-29-15 evidenced the patient's blood pressure was 194/115 at 8:19 AM, 209/122 at 8:30 AM, and 195/115 at 9:01 AM. The record failed to evidence any Clonidine had been administered as ordered.</p> <p>3. Clinical record number 5 included physician orders dated 7-1-15 and 7-29-15 that identified the physician ordered estimated dry weight (the desired weight at the end of the hemodialysis treatment) as 137 kilograms (kg).</p> <p>A. A hemodialysis treatment flow sheet dated 7-20-15 evidenced the patient's weight at the end of the treatment was 139.90 kg. The "Nursing Evaluation" states, "Pt [patient] 6.4 kg above edw [estimated dry weight]. pt has +1 pitting edema ble [bilateral lower extremities] and facial edema noted."</p>			

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	<p>B. Hemodialysis treatment flow sheets, dated 7-27-15 and 7-31-15, evidenced the patient's weight at the end of the treatment was 138.50 kg.</p> <p>C. A hemodialysis treatment flow sheet dated 7-29-15 evidenced the patient's weight at the end of the treatment was 139.10 kg.</p> <p>D. A hemodialysis treatment flow sheet dated 8-3-15 evidenced the patient's weight at the end of the treatment was 140.10 kg.</p> <p>4. Clinical record number 6 included physician orders dated 10-13-14 that state, "Treatment Medications . . . Clonidine HCl 0.1 gm oral during dialysis prn-may repeat x1."</p> <p>A. A hemodialysis treatment flow sheet dated 7-20-15 evidenced the patient's blood pressure was 187/77 at 7:07 AM, 184/75 at 7:30 AM, and 184/74 at 8:36 AM. The record failed to evidence any Clonidine had been administered as ordered.</p> <p>B. A hemodialysis treatment flow sheet dated 7-27-15 evidenced the patient's blood pressure was 182/79 at 6:39 AM and 198/82 at 7:01 AM. The</p>			

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	<p>record failed to evidence any Clonidine had been administered as ordered.</p> <p>5. Clinical record number 7 included physician orders dated 6-3-15 that identified the physician ordered estimated dry weight as 101 kg.</p> <p>A. A hemodialysis treatment flow sheet dated 7-13-15 evidenced the patient's weight at the end of the treatment was 106.3 kg.</p> <p>B. A hemodialysis treatment flow sheet dated 7-15-15 evidenced the patient's weight at the end of the treatment was 103.3 kg.</p> <p>C. A hemodialysis treatment flow sheet dated 7-20-15 evidenced the patient's weight at the end of the treatment was 103.6 kg.</p> <p>D. A hemodialysis treatment flow sheet dated 7-22-15 evidenced the patient's weight at the end of the treatment was 103.2 kg.</p> <p>E. A hemodialysis treatment flow sheet dated 7-24-15 evidenced the patient's weight at the end of the treatment was 103.3 kg.</p> <p>F. A hemodialysis treatment flow</p>			

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V 0544 Bldg. 00	<p>sheet dated 7-27-15 evidenced the patient's weight at the end of the treatment was 103.9 kg. The "Nursing Evaluation" states, "Pt has +2 pitting edema ble noted."</p> <p>G. A hemodialysis treatment flow sheet dated 8-3-15 evidenced the patient's weight at the end of the treatment was 105.5 kg.</p> <p>6. The clinic manager, employee A, was unable to provide any additional documentation and/or information when asked about the above-stated findings on 8-6-15 at 1:30 PM.</p> <p>7. 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: . . . Does of Dialysis . . . Provide necessary care and services to manage the patient's volume status."</p> <p>494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of</p>			

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	<p>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 the prescribed dose of dialysis had been maintained in 2 (#s 1 and 2) of 10 records reviewed.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included physician orders dated 7-24-15 that state, "Dialysate 3.0 K [potassium], 2.25 Ca [calcium]". Observation on 8-3-15 at 2:45 PM and 8-5-15 at 1:00 PM noted the patient was connected to the 2K 2.5 Ca dialysate outlet.</p> <p>The clinic manager, employee A, stated, on 8-5-15 at 1:00 PM, "The patient is running on the wrong dialysate."</p> <p>2. Clinical record number 2 included physician orders dated 6-19-15 that identified the patient was to receive 1000 units of bolus heparin each treatment.</p> <p>A. Hemodialysis treatment flow sheets, dated 7-10-15, 7-17-15, 7-24-15, and 7-31-15, failed to evidence any heparin had been administered as</p>	V 0544	<p>On September 11th2015 the Governing Body met to review the statement of deficiencies andto make certain that all identified deficiencies are being addressed bothimmediately and with long term resolution TheClinical Manager met with the facility Education Coordinator to arrange andschedule staff in-services to re-educate all staff members on the followingpolicies FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment andPlan of Care" With emphasis onensuring that the patient's heparin and dialysis prescription is deliveredaccording to the physician's order. This will be monitoreddaily by the nurses during their treatment review and then further reviewed bythe Clinical Manager. The Clinical Managerwill monitor the results of the treatment sheet reviews daily for 2 weeks,weekly for 4 weeks and ongoing monitoring will be determined by the QAICommittee upon review of monitoring results and resolution of the issue. The Clinical Manageris responsible to report a summary of findings monthly in QAI. If resolution isnot evident, the QAI Committee will complete a root cause analysis and the Planof Correction will be revised</p>	09/16/2015			

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V 0547 Bldg. 00	<p>ordered.</p> <p>B. The clinic manager, employee A, was unable to provide any additional documentation and/or information when asked about the above-stated findings on 8-6-15 at 1:30 PM.</p> <p>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 Plan of Care must include, but is not limited to the following: . . . Dose of Dialysis. Sustain the prescribed dose of dialysis to meet FMS target."</p> <p>494.90(a)(4) POC-MANAGE ANEMIA/H/H MEASURED Q MO The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level.</p> <p>The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. Based on clinical record and facility policy review and interview, the facility failed to provide the necessary care and services to maintain the patients' hemoglobin of greater than 10 grams per</p>	V 0547	<p>as necessary. The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body</p> <p>The Director of Operations has reviewed the following policies with the Home Program manager on 9/14/2015 and emphasized his responsibility to ensure that all direct patient</p>	09/16/2015

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	<p>deciliter (g/dL) in 2 (#s 8 and 9) of 6 records reviewed for anemia management.</p> <p>The finding include:</p> <p>1. Clinical record number 8 identified the patient as a home peritoneal dialysis patient. The record included physician orders dated 5-4-15 that evidenced the patient was to receive 8000 units of Epogen (a medication to help the body create more red blood cells) 1 time per week. An order dated 7-9-15 evidenced the Epogen had been increased to 10,000 units 1 time per week.</p> <p>A. The facility's "FMCNA Epo Control Log", for 5-14-15 through 7-1-15 and 7-8-15 through 8-3-15, evidenced 8000 units of Epogen had been administered to the patient on 6-16-15 and 10,000 units had been administered on 7-9-15 in the clinic. The log failed to evidence any Epogen had been administered to the patient the weeks of 6-21-15 and 6-28-15.</p> <p>B. The record included laboratory results that identified the patient's hemoglobin level was 9.5 on 6-16-15 and had decreased to 7.4 on 7-9-15.</p> <p>2. Clinical record number 9 included</p>		<p>care staffollow Policy and Procedure. On September 15th,2015, the Home Program Manager reviewed the "comprehensive InterdisciplinaryAssessment and Plan of Care" policy with the Dietitian, Social Worker andNursing Staff in reference to "provide the necessary care and services tomaintain the patients' hemoglobin of greater than 10 grams per deciliter(g/dl). The Home Program Manager willaudit 100% of all patients' hemoglobin and iron levels by 9/16/2015 to ensurehemoglobin and iron levels are within the appropriate physician ordered targetrange. On 8/9/2015 the Home Clinical Manager began auditing 100% of medicationadministration for all epogen and venofer administration for documentation andaccuracy. The Home Program Manager willensure compliance by auditing the medical records in accordance with QAImedical Record Auditing requirements, using the Medical Record audit tool on amonthly basis. Specifically during the medical record audits, labs results andmedication administration will be reviewed and records found incomplete, notappropriate or lacking</p>				

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V 0550 Bldg. 00	<p>physician orders dated 4-28-15 that identified 200 milligrams (mg) of Venofer (iron) was to be administered intravenously every 2 weeks. An order dated 7-1-15 evidenced 100 mg was to be administered every 4 weeks.</p> <p>The record evidenced Venofer 200 mg had been administered to the patient on 6-2-15. The record failed to evidence any Venofer had been administered the week of 6-14-15.</p> <p>3. The Home Therapies Director of Operations, employee BB, indicated, on 8-7-15 at 10:45 AM, patients numbered 8 and 9 had not received the Epogen or Venofer as ordered by the physician.</p> <p>4. 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: . . . Anemia. Provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin level."</p> <p>494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS The interdisciplinary team must provide</p>		<p>documentation of accurate medication administration will be immediately addressed and corrected. The Home Program Manager is responsible to analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review. The Director of Operations is responsible to ensure that the data required within this Plan of Correction is presented to the QAI Committee on a monthly basis for evaluation.</p>	

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	<p>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.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure employees had provided post dialysis access care in accordance with facility policy in 1 (#2) of 2 discontinuation of dialysis and post dialysis access care observations completed.</p> <p>The findings include:</p> <p>1. Employee P, a patient care technician (PCT), was observed to discontinue the dialysis treatment and provide access care to patient number 16 on 8-4-15 at 12:00 PM. The PCT was observed to remove the venous and arterial needles, one at a time, and apply gauze and tape over the insertion sites. The PCT applied a clamp over the gauze and tape to maintain pressure. After approximately 10 minutes, the PCT was observed to remove the clamps and apply more tape to the insertion sites over the existing gauze. The PCT was not observed to change the gauze after removing the clamp.</p>	V 0550	<p>On September 11th 2015 the Governing Body met to review the statement of deficiencies and to make certain that all identified deficiencies are being addressed both immediately and with long term resolution. The Clinical Manager met with the facility Education Coordinator to arrange and schedule staff in-services to educate all staff members on the following policies "FMS-CS-IC-115-013C" Post Treatment Fistula Needle Removal" procedure with emphasis placed on removing the gauze used to establish and replace the site with Band-Aids of adhesive dressing or clean tape with gauze dressing. Training will be completed by September 15th 2015 and an in-service attendance sheet is available in the facility for review. The Clinical Manager will ensure that infection control audits utilizing the QAI Infection Control audit tool are done daily for 2 weeks, weekly for 4 weeks, monthly via the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager who is responsible to</p>	09/16/2015

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V 0580 Bldg. 00	<p>2. The clinic manager, employee A, indicated, on 8-4-15 at 4:15 PM, employee P had not provided post access care in accordance with facility policies and procedures.</p> <p>3. The facility's 3-26-14 "Post Treatment Fistula Needle Removal" procedure number FMS-CS-IC-I-115-013C states, "Once hemostasis has been achieved, remove the gauze used for hemostasis and replace the sites with Band-Aids of adhesive dressing or clean tape with gauze dressing."</p> <p>Based on home program administrative record review, skilled nursing facility record review, facility policy review and interview, the facility failed to maintain compliance with this condition by failing to ensure the interdisciplinary team (IDT) had overseen the training of SNF staff to provide home peritoneal dialysis treatments to a resident of the SNF in 1 of 1 record reviewed of patients that are residents of a SNF and receive home peritoneal dialysis (See V 582); by failing to ensure home peritoneal dialysis (PD) training for skilled nursing facility (SNF)</p>	V 0580	<p>address the issue with each employee including corrective action as appropriate The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans. The QAI Committee is responsible to provide oversight until ongoing resolution has been determined The Clinical Manager is responsible to report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p> <p>The Governing Body acknowledges its responsibility to ensure that FMC Indianapolis North has a Care at Home Program that identifies a comprehensive assessment of health status and that provides required training of all required content to home-based caregivers to ensure competency. The program must provide necessary dialysis treatment oversight and monitoring to home-based caregivers in order to ensure positive</p>	09/16/2015			

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	<p>staff had been completed and included all of the required subject areas in 26 of 26 records reviewed of SNF staff training (See V 585); and by failing to ensure self-monitoring records had been reviewed for completion in 1 of 3 home records reviewed (See V 587).</p> <p>The cumulative effect of these systemic problems resulted in the facility being found out of compliance with this condition, 42 CFR 494.100 Care At Home.</p>		<p>outcomes. The Governing Body Of FMC Indianapolis Northmet upon receipt of the SOD, after review of the SOD the Governing Body determined the immediate corrections required and the following action steps were agreed upon and implemented the following steps.</p> <p>Effective Immediately:</p> <ul style="list-style-type: none"> ·The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the Condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to quarterly or as needed meetings. ·The Clinical Manager (CM) along with the Home Therapies Program Manager (HTPM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review. ·The Director of Operations will present an update on the Plan of Correction and all other actions taken toward the resolution of the deficiencies at 	

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			<p>each Governing Body meeting through to the resolution.</p> <ul style="list-style-type: none"> -The processes as noted in this POC will be reviewed by the Governing Body at each meeting. These meetings will ensure ongoing progress towards resolution of noted deficiencies is being provided. -Minutes of the Governing Body and QAI meetings, as well as monitoring forms, educational documentation will provide evidence of these actions, the Governing Body's direction and monitoring of facility activities. These will be available for review at the facility. <p>The Director of Operations for Home Therapies has reviewed the following policies with the Home Therapies Program Manager on 9/14/2015 emphasizing his responsibility to ensure all staffmembers, medical staff, and patients are educated on policies. Competencies were assessed and staff understands the requirement to follow policies and procedures as written:</p> <p>“Home Dialysis Patient Education and Training Guidelines”(Policy) FMS-CS-HT-I-200-030A, “PD Infection Control”(Policy) FMS-CS-HT-I-25-000, “Medication Management”(Policy)</p>	

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			<p>FMS-CS-HT-I-230-000, "Preparing and Adding Intraperitoneal Medications to Dialysate" (Policy) FMS-CS-HT-I-230-005A, "Preparing and Adding Intraperitoneal Medications to Dialysate" (Procedure) FMS-CS-HT-I-230-005C, "Peritoneal Dialysis Adequacy Testing" (Policy) FMS-CS-HT-I-230-010A, "Peritoneal Dialysis Adequacy Testing" (Procedure) FMS-CS-HT-I-235-010C, "Patient Home Record Keeping" (Policy) FMS-CS-HT-I-200-010A, "Patient Home Record Keeping" (Procedure) FMS-CS-HT-I-200-010C, "CAPD Daily Flowsheet" (Policy) FMS-CS-HT-I-200-010D2, "PD Access Management/Treatment" (Policy) FMS-CS-HT-I-205-000, "Managing PD Catheter Complications-Poor Flow" (Policy) FMS-CS-HT-I-205-001, "Peritoneal Access Care Guidelines For Patients Referred For PD Training and Therapy" (Policy) FMS-CS-HT-I-205-010A, "Referral and Physician Orders for Patients Receiving Peritoneal Access Care Services" (policy) FMS-CS-HT-I-205-010D3 The response provided for V582 describes in detail, the</p>	

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V 0582 Bldg. 00	494.100(a) H-IDT OVERSEES HOME TRAINING The interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in §494.10) and when the home dialysis caregiver or home dialysis modality changes. Based on home program administrative record review, interview, and skilled nursing facility (SNF) record review, the	V 0582	processes and monitoring steps taken to ensure allstaff members at a SNF prior to providing home peritoneal dialysis treatmentsto a patient from this dialysis facility have been appropriately trained. The response provided for V585 describes in detail, the processes and monitoring steps taken to ensurethat the content and scope of the facility's home dialysis training programencompasses all the required subject areas. The response provided for V587 describes in detail, the processes and monitoring steps taken to ensurethat all home dialysis patient's medical records, including self-monitoringsheets be collected, reviewed by the appropriate staff for trends, omissions orconcerns and such review share be documented. The Home Program Manager willprovide established structured training program designed to meet the trainingof	09/16/2015

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	<p>facility failed to ensure the interdisciplinary team (IDT) had overseen the training of SNF staff to provide home peritoneal dialysis treatments to a resident of the SNF in 1 (# 9) of 1 record reviewed of patients that are residents of a SNF and receive home peritoneal dialysis.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. A home visit was made to patient number 9 in the SNF on 8-6-15 at 2:25 PM. A SNF staff member (SNF staff 6) was observed to complete a peritoneal dialysis (PD) exchange on the patient. <p>The SNF staff member was observed to cleanse her gloved hands with alcohol cleanser a total of 9 times throughout the procedure. The SNF staff member was not observed to remove her gloves prior to cleansing her hands.</p> <ol style="list-style-type: none"> 2. The SNF medication administration records that included documentation of the PD exchange treatments for patient number 9, dated 6-1-15 through 6-30-15, 7-1-15 through 7-31-15, and 8-1-15 through 8-6-15, were obtained from the SNF on 8-6-15 during the home visit. The records were reviewed on 8-7-15 at 8:15 AM. The SNF treatment records identified 19 different SNF staff that had 		<p>the SNF/Caregiver. The Home Program manager or designee will provide documented training, skill check off with knowledge assessment to each caregiver prior to patient contact. The Home Program manager or designee provided retraining to SNF on 8/21/2015, 9/10/2015, 9/3/2015 and 9/8/2015. The Home Program manager will audit 100% of home records and compare caregiver signature/initials to documented training records to ensure only competent SNF are providing treatment by 9/16/2015. The audit will continue for a minimum of every two months. Any patient found to have records out of compliance will be reviewed when errors found. Education will be provided to patients and SNF as required to complete home records per policy. Home Program manager or designee will call SNF weekly times 4 weeks, then monthly to verify any staff changes and provide training to new staff prior to patient contact. Home Program manager or designee will provide retraining of existing SNF staff on an annual basis while patients present in SNF. Training records will be maintained at the facility. The Home Program Manager</p>	

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	<p>provided the PD exchanges 4 times per day for the patient.</p> <p>A. The facility's administrative records failed to evidence training records for 9 (SNF staff 2, SNF staff 3, SNF staff 4, SNF staff 8, 9, 10, 11, 15 and 18) of the 19 individuals that had provided the exchanges for the patient.</p> <p>B. The Home Therapies Director of Operations, employee BB, stated, on 8-7-15 at 10:00 AM, "I had no idea they [the SNF] were using untrained individuals [to provide the PD exchanges to patient number 9]."</p> <p>3. The facility's administrative records included a "Skilled Nursing Facility/Nursing Home Agreement For Certain Home Peritoneal Dialysis Related Services" dated 4-6-15. The agreement states, "The ESRD Dialysis Unit ESRD Staff shall provide an educational training program to train Nursing Facility Staff as the ESRD Resident's Caregiver."</p> <p>SNF staff 6 stated, on 8-6-15 at 3:05 PM, "They [the ESRD facility] had an inservice for us. The new girls follow me and another nurse that has been trained if they need to learn how to do the exchanges."</p>		<p>isresponsible to analyze and trend all data and monitoring/audit results asrelated to this Plan of Correction prior to presenting the monthly data to theQAI Committee for oversight and review. The Director of Operations isresponsible to ensure that the data required within this Plan of Correction ispresented to the QAI Committee on a monthly basis for evaluation.</p>	

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V 0585 Bldg. 00	<p>4. The Home Therapies Director of Operations, employee BB, stated, on 8-7-15 at 10:15 AM, "We do not have any specific policies and procedures for training SNF staff."</p> <p>5. The facility's 6-19-13 "Home Dialysis Patient Education and Training Guidelines" policy number FMS-CS-HT-I-200-030A states, "Training must be documented in the patient medical record and must include evidence of patient/care partner demonstrated competence in performing the home dialysis procedures."</p> <p>494.100(a)(3) H-TRAIN CONTENT INCLUDES ER PREP HOME PTS The training must-</p> <p>(3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:</p> <p>(i) The nature and management of ESRD.</p> <p>(ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.</p> <p>(iii) How to detect, report, and manage potential dialysis complications, including</p>			

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	<p>water treatment problems.</p> <p>(iv) Availability of support resources and how to access and use resources.</p> <p>(v) How to self-monitor health status and record and report health status information.</p> <p>(vi) How to handle medical and non-medical emergencies.</p> <p>(vii) Infection control precautions.</p> <p>(viii) Proper waste storage and disposal procedures.</p> <p>Based on administrative record and facility policy review and interview, the facility failed to ensure home peritoneal dialysis (PD) training for skilled nursing facility (SNF) staff had been completed and included all of the required subject areas in 26 (#s 1 through 26) of 26 records reviewed of SNF staff training.</p> <p>The findings include:</p> <ol style="list-style-type: none"> The facility's administrative records included training records for SNF staff at the SNF where patient number 9 resides. The records, dated 4-8-15, evidenced the only subject area addressed for SNF staff 5, 6, 7, 15, 17, 19, 20, 21,22, 23, 24, and 25 was the use of the "Stay-Safe Exchange Set CAPD [continuous ambulatory peritoneal dialysis] System." The records failed to evidence any of the other required subject areas had been addressed. The Home Therapies Director of Operations, employee BB, indicated, on 	V 0585	<p>The Director of Operations reviewed the following training materials regarding the use of patient education on 8/24/2015: "Right Start at Home", "PD Getting Started", and "PD Home Therapy Training Checklist". The Home Program Manager will reeducate the Home Program Interdisciplinary team 8/24/2015 on the home training materials listed above to ensure appropriate home training to patient, designated care giver, or self-dialysis patient before the initiation of home dialysis or self-dialysis. Training topics include:</p> <ul style="list-style-type: none"> · Knowledge & Skills Checklist · Correct procedure for performing a manual peritoneal dialysis exchange (CAPD) with return demonstration. · Infection control concepts with return demonstration. · Main steps of CAPD treatment and return demonstration. · Home environment and supplies. 	09/16/2015

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	<p>8-7-15 at 9:45 AM the facility had reviewed the training provided to the SNF staff in April and had found it to be lacking. The director indicated the training had been revised in May 2015.</p> <p>The facility's administrative records included training records for SNF staff 12, 14, 23, and 26, dated 5-26-15. These records failed to evidence the training had addressed (3)(ii) effective administration of erythropoiesis-stimulating agents (if prescribed); (3)(iii) how to detect, report, and manage potential dialysis complications; (3)(vii) infection control precautions (to include hand hygiene and glove changes); and (3)(viii) proper waste storage and disposal procedures.</p> <p>3. The facility's administrative records failed to evidence training that addressed any of the required subject areas had been provided to SNF staff. The facility's administrative records failed to evidence training records for 9 (SNF staff 2, SNF staff 3, SNF staff 4, SNF staff 8, 9, 10, 11, 15 and 18) of the 19 individuals that had provided the exchanges for the patient.</p> <p>4. Employee V, a home therapies registered nurse (RN), stated, on 8-7-15 at 8:45 AM, "I am the one that does the</p>		<ul style="list-style-type: none"> ·Kidney diseaseknowledge. ·Components ofdialysis solution. ·Signs andsymptoms of peritonitis, exit site infection, increased blood pressure,decreased blood pressure, fluid overload and dehydration. ·Troubleshootingand managing complications. ·Medications.Effective administration of erythropoeiten stimulating agents to achieve andmaintain target level hemoglobin. ·Nutrition. ·Wastedisposal. ·AnemiaManagement. ·Home Emergencypreparedness. The Home Program manager ordesignee provided retraining to SNF on 8/21/2015, 9/102015, 9/3/2015 and9/8/2015. The Home Program manager ordesignee provided documented retraining, skill check off with knowledgeassessment to each caregiver in SNF The monthly audit resultswill be presented at the monthly QAI meeting by the Home Program Manager. TheQAI committee is responsible to review analyze, and trend all monitoringresults to ensure resolution is occurring and sustained. 	

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	<p>SNF staff training." The RN stated further, "I discuss what dialysis does, how it controls fluids, how dialysis works, and the percentages of the dialysate used for PD. I then demonstrate an exchange and have each individual does an exchange. The training takes about 4.5 hours."</p> <p>The RN was unable to provide a course outline or agenda when asked on 8-7-15 at 8:45 AM.</p> <p>5. The facility's 6-19-13 "Home Dialysis Patient Education and Training Guidelines" policy number FMS-CS-HT-I-200-030A states, "The following are requirements for home dialysis training for the patient and/or care partner: . . . 3. At a minimum, content areas that must be included in the home dialysis training program include the following: The nature and management of ESRD. Specific (step-by-step) instructions in home dialysis procedures for home hemodialysis or peritoneal dialysis to facilitate adequate dialysis as prescribed by the patient's physician. Training in proper storage and administrations of ESA's, if applicable. Training in proper storage, preparation and administration of other physician ordered medications in the home environment. Detecting,</p>			

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V 0587 Bldg. 00	<p>managing and reporting potential dialysis complications, including water treatment problems as applicable. Availability of support services and how to access and use these resources. Self-monitoring of health status including recording and reporting of health status information. Completing and presenting home dialysis documentation such as treatment sheets, IQ card and/or computer USB drive and technical logs to the facility for monthly review. Handling medical and non-medical emergencies. Infection control precautions including disposal of biohazard waste."</p> <p>6.</p> <p>494.100(b)(2),(3) H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS The dialysis facility must - (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient ' s medical record. Based on clinical record and facility policy review and interview, the facility failed to ensure self-monitoring records had been reviewed for completion in 1 (# 8) of 3 home records reviewed.</p>	V 0587	The Director of Operations reeducated the Clinical and Home Therapy Program manager during the staff inservice on 9/16/2015 reviewed with RN staff the Conditions for coverage: FAC	09/16/2015

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V 0710 Bldg. 00	<p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 8 included self-monitoring peritoneal dialysis daily home records for 5-29-15 through 7-22-15. The home records failed to denote the dextrose solution used for the last exchange of the day. The record failed to evidence the registered nurse (RN) had reviewed the records and noted the lack of documentation of the type of dextrose solution used. 2. The Home Therapies Director of Operations, employee BB, stated, on 8-5-15 at 9:05 AM, "The record does not include documentation the RN asked the patient what dialysate was used for the last fill." 3. The facility's 3-7-12 "Patient Home Record Keeping" policy number FMS-CS-HT-I-200-010A states, "Home records will be reviewed by Home Program nursing staff during patient monthly clinic visits to identify trends or omissions." <p>Based on observation, interview, and review of facility policy, it was</p>	V 0710	<p>received/Review PTRRecords Q2 Months as detailed in FMS policy FMS-CT-HT-200-010A "Patient HomeRecord Keeping." The Home Program manager willcomplete 100% chart audit of all patients' monthly visit sheet by 9/16/2015 toensure that all patients have documentation showing that their home recordsheets have been reviewed a minimum of every two months. Any patient found out of compliance,including #8 will be reviewed at the next monthly clinic. Education will beprovided to patients as required to complete home records per policy. The Home Program Manager is responsible to reporta summary of findings monthly utilizing the medical record audit tool to theQAI committee. The QAI committee isresponsible to analyze the results and determine a root cause analysis and newPlan of Action if resolution is not occurring. Ongoing compliance will be monitored by the QAI committee.</p> <p>The Governing Bodyacknowledges its</p>	09/16/2015			

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	<p>determined the facility failed to maintain compliance with this condition by failing to ensure policies and procedures had been developed for the training of skilled nursing facility (SNF) staff to provide home dialysis treatments to residents of the SNF (See V 714) and by failing to ensure the facility's intravenous medication administration policies and procedures had been adhered to by all staff in 1 of 3 intravenous medication administration observations completed (See V 715).</p> <p>The cumulative effect of these systemic problems resulted in the facility being found out of compliance with 42 CFR 494.150 Responsibilities of the Medical Director.</p>		<p>responsibility to ensure that the Medical Director of FMCIndianapolis North actively participates in the development, review and implementation of patient care policies and procedures as well as adherence by all facility staff to the facility's policies and procedures. This responsibility includes reviewing and approving an organized course of training to be provided to patient/carepartners who express interest in and who elect home dialysis as a treatment modality. The Director of Operations met with the Medical Director on September 11th, 2015 to review his requirements as defined in the Condition for coverage and Medical Staff Bylaws to ensure that all policies and procedures relative to patient admission, patient care, infection control and patient safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers. The Director of Operations specifically reviewed with the Medical Director on his responsibility to provide oversight of staff training, including the competencies of the staff and</p>	

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			<p>adherence to the policies adopted at this facility. The Director of Operations for Home Therapies met with the Medical Director and reviewed the FMS-CS-HT-I-200-030A "HomeDialysis patient education and Training Guidelines" policy as well as the following patient education training materials: "Right Start at Home", PD Getting Started", and "PD Home Therapy Training Checklist". The Governing Body and the Medical Director, whom is a member of this Governing Body, met upon receipt of the SOD, after review of the SOD the Governing Body and Medical Director determined the immediate corrections required and the following action steps were agreed upon and implemented the following steps. Effective Immediately:</p> <ul style="list-style-type: none"> ·The Governing Body will meet weekly to monitor the progress of the Plan of Correction until the condition level deficiencies are lifted, then monthly for an additional three months to ensure that the corrective actions have resulted in resolution of the cited issues. Once this is determined, the Governing Body will return to quarterly or as needed meetings. ·The Clinical Manager (CM) 	

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			<p>along with the Home Therapies Program Manager (HTPM) will analyze and trend all data and monitoring/audit results as related to this Plan of Correction Prior to presenting the monthly data to the QAI committee for oversight and review.</p> <ul style="list-style-type: none"> The Director of Operations will present an update on the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing body meeting through the resolution. The processes as noted in this POC will be reviewed by the Governing body at each meeting. These meetings will ensure ongoing progress towards resolution of noted deficiencies is being provided Minutes of the Governing body and QAI meeting, as well as monitoring forms, educational documentation will provide evidence of these actions, the Governing Body's direction and monitoring of facility activities. These will be available for review at the facility. The response provided for V714 describes in detail, the processes and monitoring steps taken by both the Medical Director and governing Body to ensure that the facility is in full compliance with the expectations and 	

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V 0714 Bldg. 00	<p>494.150(c)(1) MD RESP-DEVELOP, REVIEW & APPROVE P&P The medical director must-</p> <p>(1) Participate in the development, periodic review and approval of a "patient care policies and procedures manual" for the facility;</p> <p>Based on home program policy and procedure manual review and interview, the medical director failed to ensure policies and procedures had been developed for the training of skilled nursing facility (SNF) staff to provide home dialysis treatments to residents of the SNF.</p> <p>The findings include:</p>	V 0714	<p>guidelines noted in the "Home Dialysis Education and Training Guideline" policy. The response provided for V715 describes in detail, the processes and monitoring steps taken by both the Medical Director and Governing Body to ensure that the facility staff are trained, competent and fully comply with the policies and procedures adopted for use at this facility, including but not limited to the ensuring the facility's intravenous medication administration policies and procedures had been adhered to by all staff.</p> <p>At the direction of the Medical Director, the Director of Operations for Home Therapies reviewed the FMS-CS-HT-I-200-030A "Home Dialysis patient Education and Training Guidelines" policy as well as the following patient education training materials: "Right Start at Home", "PD Getting Started", and "PD Home Therapy Training Checklist" on 09/16/2015 with</p>	09/16/2015

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	<p>1. The home program patient care policy and procedure manual failed to evidence policies and procedures for the training of SNF staff to provide peritoneal dialysis treatments to residents of a SNF.</p> <p>2. The Home Therapies Director of Operations, employee BB, stated, on 8-7-15 at 10:15 AM, "We do not have any specific policies and procedures for training SNF staff."</p>		<p>the Home Program Interdisciplinary team. As required by this policy, the home IDT organized the training course to include but not limited to the following training topics:</p> <ul style="list-style-type: none"> • The nature and management of ESRD • Specific (step-by-step) instructions on using the prescribed patient equipment • Specific (step-by-step) instructions in home dialysis procedures for home hemodialysis or peritoneal dialysis to facilitate adequate dialysis as prescribed by the patient's physician • Training in proper storage and administration of ESA's, if applicable • Training in proper storage, preparation and administration of other physician ordered medications in the home environment • Detecting, managing and reporting potential dialysis complications, including water treatment problems as applicable • Availability of support services and how to access and use these resources • Self-monitoring of health status including recording and reporting of health status information • Completing and presenting home dialysis documentation such as treatment sheets, IQ card and/or computer USB drive and technical logs to the facility for monthly review • Handling medical and non-medical emergencies 	

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			<p>Infection control precautions including disposal of biohazard waste. The training material and documentation to be used in this training course will be: "Right Start at Home", "PD Getting Started", and "PD Home Therapy Training Checklist". The training course will be reviewed and adopted at the Governing Body meeting on 8/19/2015. The peritoneal dialysis home training materials and checklist will be completed by the home dialysis nurse and patient/home partner. At the completion of the training program the checklist will be kept in the patient's medical record under the "Training" tab. The Home Clinic manager will ensure on-going compliance by auditing the medical records in accordance with QAI Medical Record Auditing requirements, using the Medical Record audit tool on a monthly basis. Specifically during the medical record audits, the training material will be reviewed to ensure completion of all required training topics. Training records found incomplete will be immediately addressed and corrected. The Home Program Manager will provide established structured training program designed to meet the</p>	

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			<p>training of the SNF/Caregiver on 8/21/2015. The Home Program manager or designee will provide documented training, skill check off with knowledge assessment to each caregiver prior to patient contact. The Home Program manager or designee provided retraining to SNF on 8/21/2015, 9/10/2015, 9/3/2015 and 9/8/2015. The Home Program manager will audit 100% of home records and compare caregiver signature/initials to documented training records to ensure only competent SNF are providing treatment. Home Program manager or designee will call SNF weekly to verify any staff changes and provide training to new staff prior to patient contact. Home Program manager or designee will provide retraining of existing SNF staff on an annual basis while patients present in SNF. The Home Program Manager is responsible to analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review. The Director of Operations is responsible to ensure that the data required within this Plan of Correction is presented to the QAI</p>	

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V 0715 Bldg. 00	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must-</p> <p>(2) Ensure that-</p> <p>(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers;</p> <p>Based on observation, interview, and review of facility policy and procedure, the medical director failed to ensure the facility's intravenous medication administration policies and procedures had been adhered to by all staff in 1 (# 3) of 3 intravenous medication administration observations completed.</p> <p>The findings include:</p> <p>1. Employee AA, a home program registered nurse (RN), was observed to administer intravenous Venofer (iron) to patient number 8 on 8-5-15 at 2:20 PM. The RN was observed to insert a butterfly intravenous needle and tubing into the patient's right antecubital area. The RN obtained a blood sample and then noted she had forgotten to prepare the Venofer for administration.</p> <p>A. The Home Therapies Director of</p>			V 0715	<p>Committee on a monthly basis for evaluation.</p> <p>The Director of Operations met with the Medical Director on September 11th 2015 to review his requirements as defined in the Condition for Coverage and Medical Staff Bylaws. Included in this review was the Medical Directors responsibility for ensuring the facility's intravenous medication administration policies and procedures are adhered to by all staff. The Director of Operations also reviewed the Plan of Correction to be instituted to correct this issue. The Medical Director approved and directed the implementation of the plan as noted below. The Director of Operation has reviewed the following policies with the Home Program Director of Operations and Home Program manager on 9/16/2015 and emphasized their responsibility to ensure that all patient care staff follow</p>		09/16/2015

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	<p>Operations (HTDO), employee BB, left the room and returned several minutes later with 3 syringes in her hand and placed them on a clean field on a table for employee AA. The HTDO indicated she had drawn up the ordered amount of Venofer and the other two approximately 5 milliliter syringes contained sterile water. The HTDO was asked about the sterile water. She stated, "That is what we use."</p> <p>B. The RN, employee AA, removed the butterfly needle and tubing from the patient's arm because it had clotted and was no longer usable. The RN inserted another butterfly needle and tubing. The RN was observed to clear the line with the first syringe containing the sterile water and then administer the Venofer. The RN then injected the second syringe of sterile water into the patient.</p> <p>2. The Medical Director, employee CC, stated, on 8-7-15 at 8:20 AM, "[The use of the sterile water] should never have happened." The Medical Director indicated he thought the error occurred due to a "lack of home experience."</p> <p>3. The facility's 1-28-15 "Medication Preparation and Administration" policy number FMS-CS-IC-I-120-040A states, "The person who prepares the medication</p>		<p>Policy and Procedure.</p> <ul style="list-style-type: none"> -Medication Preparation and Administration (FMS-CS-IC-I-120-040A) -Peritoneal Dialysis Venofer Administration Procedure (FMC-CS-HT-I-230-040C) <p>The Home Program Manager will audit 100% of all patients' hemoglobin and iron levels by 9/18/2015 to ensure hemoglobin and iron levels are within the appropriate physician ordered target range. On 8/9/2015 the Home Clinical Manager began auditing 100% of medication administration for all epogen and venofer administration for documentation and accuracy. The Home Program Manager will ensure compliance by auditing the medical records in accordance with QAI Medical Record Auditing requirements, using the Medical Record audit tool on a monthly basis. Specifically during the medical record audits, labs results and medication administration will be reviewed and records found incomplete, not appropriate or lacking documentation of accurate medication administration will be immediately addressed and corrected. The Home Program Manager is responsible to analyze and</p>	

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	<p>must be the person who will administer the medication."</p> <p>4. The facility's 11-9-11 "Peritoneal Dialysis Venofer Administration Procedure" number FMS-CS-HT-I-230-040C states, "Insert IV into peripheral vein per procedure . . . utilizing aseptic technique. Secure with tape, aspirate air from tubing and flush with normal saline . . . After Venofer infusion is complete, flush IV with enough normal saline to clean the line."</p> <p>5. Observation noted, on 8-6-15 at 12:30 PM, vials of 10 milliliter single dose sterile water in cabinets in the home program medication preparation area. The vials indicate they are for single dose use and state, "FOR DRUG DILUENT USE . . . do not give intravenously unless rendered nearly isotonic."</p>		<p>trend all data and monitoring/audit results asrelated to this Plan of Correction prior to presenting the monthly data to theQAI Committee for oversight and review. The Director of Operations isresponsible to ensure that the data required within this Plan of Correction ispresented to the QAI Committee on a monthly basis for evaluation.</p>	