

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152501	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	X3) DATE SURVEY COMPLETED 09/30/2015
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE GARY	STREET ADDRESS, CITY, STATE, ZIP CODE 3290 GRANT ST GARY, IN 46408
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V 0000 Bldg. 00	<p>This visit was for an ESRD recertification survey.</p> <p>Survey dates: 9/24/15, 9/25/15, 9/28/15, 9/29/15, 9/30/15</p> <p>Facility #: 005148</p> <p>Medicare #: 152501</p> <p>Medicaid vendor #: 100275180A</p> <p>124 Incenter Hemodialysis patients 22 Peritoneal Dialysis patients</p>	V 0000		
V 0111 Bldg. 00	<p>494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and</p>			

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

TITLE

(X6) DATE

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

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	<p>monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>Based on record review, observation, and interview, the facility failed to ensure the treatment floor had been kept free of trash and kept clean in 1 of 2 observations on 9/24/15.</p> <p>The findings include:</p> <ol style="list-style-type: none"> The facility policy titled "Housekeeping" with a date of March 20, 2013 stated, "All areas must be kept clean and organized, including but not limited to the treatment area, water / supply room and offices ... Regulated Medical Waste ... shall be kept in a container that is closeable, leak proof and labeled and / or color coded." On 9/24/15 at 1:50 PM, observation on the Incenter hemodialysis treatment floor noted plastic caps on the floor around station #13 and station #17. Behind stations #15 and #16, a soiled wall connection box for the dialysate connectors was noted. The wall connector box had pieces of paper, plastic, and soiled stains in the water drainage area. At the dirty sink near the isolation room, a bleach container with 1:100 bleach water was noted to have a 	V 0111	<p>The Clinic Manager and Patient Care Technicians (PCTs) immediately cleaned the treatment area (inclusive of sink and under cabinet near isolation, wall connection boxes, and lab refrigerator), water/supply/biohazard rooms (inclusive of bicarbonate and acid tank areas and vinegar cart). The bleach container was immediately discarded and replaced with a new container. The cabinet hinges were replaced on 10-22-15. The cleaning company used for this clinic stripped and waxed the treatment floors on regularly scheduled date of 9-24-15 and removed all water stains from the floors.</p> <p>On 10-15-15 the Director of Operations reviewed with the Clinical Manager and by 10-30-15 the Clinical Manager re-will train all clinic staff on:</p> <ul style="list-style-type: none"> ·Policy FMS-CS-IC-II-155-116A Housekeeping Policy: ·Policy: General Housekeeping <ul style="list-style-type: none"> ·All areas must be kept clean and organized, including but not limited to the treatment area, water/supply/biohazard rooms and offices ·Staff responsibilities related to maintaining a clean and sanitary environment <p>The meeting agenda and</p>	10/30/2015

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	<p>black sediment lining the inside of this white container. There was approximately 2 liters of bleach water in this container. This sink had a mildewed odor and was noted to be soiled in the cabinet area under the sink. At station #22 there were plastic pieces of trash on the floor. In the lab refrigerator, there were several specimen containers which were tipped over on their sides and not in biohazard bags. There was a yellow liquid spilled inside this refrigerator and a soiled layer inside the shelves of this refrigerator. Coating the floor between station #3 where patient #15 was seated and station #4 where patient #14 was seated was a water stain with gray colored foot prints embedded into this stain.</p> <p>On 9/24/15 at 2 PM, the clinic manager indicated the treatment floor including the sink near the isolation room, the bleach container, wall connection box, and the refrigerator were not clean.</p> <p>3. In the supply room, water treatment areas and biohazard room, on 9/24/15 at 2:40 PM, a white powder was observed to be spilled onto a raised pallet bed near the bicarb tank. The vinegar cart in the storage area was noted to be very soiled.</p>		<p>attendance records will be available for review at the facility. The Clinical Manager and or designee will perform FlashPatient Treatment Area and Infection Control Audits for compliance according to the QAI Workflow Calendar, address identified issues, and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure that all areas including the treatment floor, supply/water/biohazard areas are kept clean and free of trash.</p>		

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	<p>The acid tank had soilage under it including an old piece of paper stuck to the floor under the tank. The biohazard waste room had 3 gloves laying on the floor not in the biohazard bags or containers. The biohazard room was off to the side of the supply room.</p> <p>On 9/24/15 at 2:50 PM, Employee E, the biomedical technician, indicted the supply room, biohazard room, and water treatment area were not clean.</p> <p>4. On 9/24/15 at 5 PM, the four sinks on the interior section of the treatment floor were found to have rusty hinges which left a soiled residue in the closed cabinet under these sinks.</p> <p>On 9/24/15 at 5:05 PM, the administrator indicated the sinks were rusted underneath and did not look clean.</p>			

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V 0115 Bldg. 00	<p>494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure personal protective equipment was utilized appropriately in 2 of 2 patient care observations of central venous catheter initiation and exit site care (Employee G, patient care technician, with Patient #1 and Employee H, patient care technician, with patient #13).</p> <p>The findings include</p> <p>1. On 9/25/15 at 10:30 AM, Employee G, Patient Care Technician (PCT), was observed to complete initiation of dialysis with a central venous catheter with patient #1. Employee G had donned</p>	V 0115	<p>On 10-15-15 the Director of Operations reviewed with the Clinical Manager and by 10-30-15 the Clinical Manager will re-train all clinicstaff on:</p> <ul style="list-style-type: none"> ·FMS-CS-IC-II-155-080A Personal Protective Equipment Policy: ·Personal protective equipment such as a full face shield or mask and protective eyewear with full side shield, fluid-resistant gowns and gloves will be worn to protect and prevent employees from blood or other potentially infectious materials to pass through to or reach the employee's skin, eyes, mouth, other mucous membranes, or work clothes when performing procedures during which spurting or spattering of blood might occur 	10/30/2015

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	<p>a mask but not applied the mask completely over her nose. The mask was placed under her nose and did not cover the nostrils during the entire procedure.</p> <p>2. On 9/29/15 at 6:50 AM, Employee H, PCT, was observed to complete initiation of dialysis with a central venous catheter with patient #13. Employee H had a gown on with a hole in the gown around the employee's abdominal area. The hole was approximately 1 1/2 inches in diameter.</p> <p>3. The policy titled "Personal Protective Equipment" with a date of March 20, 2013 stated, "Personal protective equipment such as a full face shield or mask and protective eyewear with full sideshield, fluid - resistant gowns and gloves will be worn to protect and prevent employees from blood or other potentially infectious materials to pass through to or reach the employee's skin, eyes, mouth, other mucous membranes, or work clothes when performing procedures during which spurting or spattering of blood might occur [e.g. (for example) initiation and termination of dialysis] ... personal protective fluid resistant gowns shall be changed whenever visibly soiled or in disrepair."</p> <p>4. On 9/30/15 at 10:30 AM, Employee</p>		<p>(e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood).</p> <ul style="list-style-type: none"> ·Personal protective fluid resistant gowns shall be changed whenever visibly soiled or in disrepair. Fluid resistant gown may be reused by the original owner for as long as it is clean and intact. ·FMS-CS-IC-I-105-002A Initiation or Treatment Using CVC Policy and FMS-CS-IC-I-105-032C Changing the Catheter Dressing Procedure ·The patient and staff must wear mask that covers their nose and mouth for all procedures that require accessing catheter <p>The meeting agenda and attendance records will be available for review at the facility.</p> <p>The Clinical Manager and or designee will perform Infection Control Audits for compliance according to the QAI Workflow Calendar, address identified issues, and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand.</p> <p>The Clinical Manager is responsible and the QAI Committee monitors to ensure PPE is utilized appropriately.</p>		

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V 0121 Bldg. 00	<p>A, the alternate administrator, indicated personal protective equipment be worn correctly and be intact during initiation of dialysis treatments.</p> <p>494.30(a)(4)(i) IC-HANDLING INFECTIOUS WASTE [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- (i) Handling, storage and disposal of potentially infectious waste;</p> <p>Based on observation, interview, and record review, the facility failed to ensure potentially infectious waste containers were stored properly in 1 of 1 observation of the biohazard room on 9/24/15.</p> <p>Findings include:</p> <p>1. In the supply room and water treatment areas, on 9/24/15 at 2:40 PM, it</p>	V 0121	<p>The biohazard waste room was immediately cleaned and gloves on the floor were disposed of in the proper biohazard container. On 10-15-15 the Director of Operations reviewed with the Clinical Manager and by 10-30-15 the Clinical Manager will re-train all clinic staff on:</p> <ul style="list-style-type: none"> ·Policy FMS-CS-IC-II-155-116A HousekeepingPolicy: ·Policy: General housekeeping ·All areas must be kept clean and organized,including but 	10/30/2015

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	<p>was observed that the biohazard waste room had 3 gloves laying on the floor not in the biohazard bags or containers.</p> <p>On 9/24/15 at 2:50 PM, Employee E, the biomedical technician, indicted the biohazard room was not clean and gloves should be discarded into the biohazard containers.</p> <p>2. The policy titled "Housekeeping" with a date of March 20, 2013 stated, "All areas must be kept clean and organized ... Regulated medical waste ... shall be placed in a container that is closeable, leak proof and labeled and / or color coded ... regulated waste must be kept separate from regular waste in a secured area ... before being removed, such containers shall be closed.</p>		<p>not limited to the treatment area, water/supply room and offices.</p> <ul style="list-style-type: none"> ·Policy: Regulated Medical Waste ·Regulated medical waste (other than sharps) shall be placed in a container that is closeable, leak proof and labeled and/or color-coded ·Regulated waste must be kept separate from regular waste in a secured area, the door must be labeled ·Before being removed, such containers shall be closed. The containers must be closed prior to being full and prior to being removed The meeting agenda and attendance records will be available for review at the facility. The Clinical Manager and or designee will perform Infection Control Audits for compliance according to the QAI Workflow Calendar, address identified issues, and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure potentially infection waste is stored properly. 		

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V 0218 Bldg. 00	<p>494.40(a) HOT H2O DISINF SYS-MONITORING 6.3.4 Bacterial control devices 6.3.4.3 Hot water disinfection systems: monitoring Hot water disinfection systems should be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Also, hot water disinfection should be performed at least as often as recommended by the manufacturer. The temperature of the water should be recorded at a point farthest from the water heater-that is, where the lowest water temperature is likely to occur ...and measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection should be maintained. Successful completion is defined as meeting temperature and time requirements specified by the equipment manufacturer.</p> <p>Based on record review and interview, the facility failed to ensure the record of daily machine disinfection with heat cycle was documented clearly for 1 of 1 facility.</p> <p>The findings include:</p> <p>1. A facility document titled "Record of Daily Machine Disinfection with Heat Cycle" with dates of 6/22/15, 6/23/15, 6/24/15, 6/25/15, and 6/27/15. The column titled "Heat or Bleach" on 6/22/15 included entries for the machines at stations #1 - 24. This column</p>	V 0218	<p>All staff were immediately instructed 9-25/26-2015 on proper documentation on the heat/disinfection log and instructed not to "writeover" an error entry.</p> <p>On 10-15-15 the Director of Operations reviewed with the Clinical Manager and by 10-30-15 the Clinical Manager will train all clinic staff on:</p> <ul style="list-style-type: none"> ·153-030-010 Disinfection Standards for Equipment: ·Documentation records will include date(s) of disinfection, residual concentration of disinfection, signature(s) of person who performed the procedure and tested for the absence of disinfectant ·Write overs are not allowed 	10/30/2015	

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	<p>completed by Employee I, Patient Care Technician [patient care technician] which included writeovers for the column titled "Heat or Bleach." A "B" had been written over with a "H" in all 24 entries for this date. The letter "B" was identified as "Bleach disinfection" and the letter "H" for "Heat disinfection." A column entry titled "Mach. [machine] No.[number] with a date of 6/27/15 evidenced machine numbers which were difficult to read. These machine numbers evidenced documentation with writeovers by Employee J, PCT. The machine number "20" had an "8" under the "O". The machine number "15" had a "3" under the "1". Two numbers were completely scribbled and could not be read of the 24 numbers under this column's documentation.</p> <p>2. On 9/25/15 at 2 PM, Employee K, biomedical supervisor, and Employee E, biomedical technician, indicated the logs were not completed correctly. The writeovers should not have occurred since this made the document difficult to read.</p> <p>3. The procedure titled "Fresenius 2008 H: Acid Clean and Chemical Disinfection" with a date of September 15, 2010 stated, "Record the machine disinfection on the dialysis machine</p>		<p>as documentation is difficult to read The meeting agenda and attendance records will be available for review at the facility. The Biomedical Technician will perform audits for compliance according to the QAI Workflow Calendar, notify the Clinical Manager if issues are identified for follow up as indicated, and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure the record of daily machine disinfection w/heat cycle is documented clearly.</p>		

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V 0401 Bldg. 00	<p>check log to provide documentation of dates that hemodialysis machine was disinfected ... references heat disinfection of the Fresenius 2008 H Hemodialysis machine."</p> <p>494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.</p> <p>Based on observation, interview, and record review, the dialysis facility failed to ensure the registered nurse administered the medication according to facility policy for 1 of 2 observations of parenteral medication administration (Employee F, Registered Nurse with patient #11) on the incenter hemodialysis treatment floor.</p> <p>The findings include:</p> <p>1. The agency policy titled "Medication</p>	V 0401	<p>On 10-15-15 the Director of Operations reviewed with the Clinical Manager and by 10-30-15 the Clinical Manager will re-train all Registered Nurses(RNs) on: ·FMS-CS-IC-I-120-011A Special Considerations:Venofer: ·Venofer may be administered undiluted as a slow intravenous injection over 2 to 5 minutes, or as an infusion of 100 mg diluted in a maximum of 100 mL of 0.9% NaCl over a period of at least 15 minutes, perconsecutive hemodialysis session The meeting agenda and attendance records will be available for review at the facility.</p>	10/30/2015	

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	<p>Preparation and Administration" with a date of January 28, 2015 stated, "Follow the principles below for medication preparation and administration. Follow the '6 Rs' of medication administration when drawing up and giving medications. The '6' Rs are Right Drug, Right Dose, Right Route, Right Time, Right Patient, Right Documentation."</p> <p>2. The agency policy titled "Special Considerations: Venofer" with a date of July 4, 2012 stated, "Venofer may be administered undiluted as a slow intravenous injection over 2 to 5 minutes or as an infusion of 100 mg [milligram] diluted in a maximum of 0.95 NaCl [sodium chloride] over a period of at least 15 minutes, per consecutive hemodialysis session."</p> <p>3. On 9/29/15 at 7:30 AM, Employee F, Registered Nurse, was observed to care for patient # 11 who was receiving hemodialysis at station #5 at machine #14 by administering 50 mg of undiluted venofer or iron sucrose into the venous line of the hemodialyis machine by intravenous push over a time span of less than 3 seconds.</p> <p>4. A treatment sheet for 9/29/15 evidenced patient #11 received Venofer or Iron Sucrose 50.00 / mg / intravenous</p>		<p>The Clinical Manager and or designee will perform Medication Audits for compliance according to the QAI Workflow Calendar, address identified issues, and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure RNs administer medications(Venofer) according to facility policy.</p>	

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	<p>push 1 times a week. This medication was given by Employee F on 9/29/15 at 7:30 AM. The patient was at station #5 with machine #14. This patient's birthday evidenced this was an adult patient.</p> <p>5. A document titled "Venofer [Iron Sucrose Injection] with a date of 2000 stated, "Dosage and administration Venofer must be administered intravenously either by slow injection or by infusion ... Adult patients with hemodialysis dependent - chronic kidney disease Administer Venofer 100 mg undiluted as a slow intravenous injection over 2 - 5 minutes or as an infusion of 100 mg diluted in a maximum of 100 mL [milliliter] 0.9 NaCl [sodium chloride] over a period of 15 minutes." [this document was an insert that was in the box with the Venofer medication.]</p> <p>6. On 9/29/15 at 8:45 AM, the alternate administrator indicated the venofer was to be administered slow push.</p>			

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V 0541 Bldg. 00	<p>494.90 POC-GOALS=COMMUNITY-BASED STANDARDS The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p> <p>Based on record review and interview, the facility failed to ensure plans of care were individualized to address the patients needs and specified parameters for the administration of as needed medications in 3 of 7 incenter hemodialysis clinical records (#1, #3, #5) reviewed.</p> <p>The findings include:</p>	V 0541	<p>On 10-15-15 the Director of Operations reviewed with the Clinical Manager and by 10-30-15 the Clinical Manager will re-train all RegisteredNurses (RNs) on: ·FMS-CS-IC-II-150-033A: Physician Order Documentation Policy with emphasis on: ·Responsibility: It is the nurses' responsibility to ensure that all treatments, medications, labs or any care provided to the patient have an accurately documented physician order (inclusive of medication administration parameters as applicable for</p>	10/30/2015	

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	<p>1. Clinical record #1 included a "Patient Plan of Care" established by the interdisciplinary team on 7/27/15. The plan of care failed to evidence the development of any goals for the diagnosis of diabetes mellitus identified on a comprehensive RN (Registered Nurse) assessment completed on 7/8/15 and a office visit document with the patient's cardiologist on 7/13/15 included in the clinical record.</p> <p>On 9/26/15 at 4:30 PM, the clinic manager indicated the plan of care was not complete.</p> <p>2. Clinical record #3 included physician orders dated 4/23/15 that state, "Clonidine HCL 0.20 mg [milligrams] oral during dialysis prn [as needed]. The order failed to evidence blood pressure parameters for the administration of the medication. The record also included order dated 5/14/15 that stated "Clonidine 0.1 mg oral prn."</p> <p>On 9/29/15 at 12:45 PM, Employee D, Registered Nurse, did not have an accurately documented physician orders since there were no blood pressure parameters given for when this medication would be given.</p> <p>3. Clinical record #5 included physician</p>		<p>prnmedications).</p> <p>·Writing Physician Orders: The nurse isobligated to verify any order which is otherwise unclear or questionable</p> <p>The meeting agenda and attendance records will be available for review at the facility. By 10-30-15 all prn medication orders will be reviewed and, with the MD, updated to include parameters for administration as applicable. Going forward and as part of obtaining prn orders, parameters will be documented if indicated.</p> <p>The Clinical Manager and or designee will perform Medical Record Audits for compliance according to the QAI Workflow Calendar, address identified issues, and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand.</p> <p>The Clinical Manager is responsible and the QAI Committee monitors to ensure POCs are individualized to address the patients' needs and specified parameters for the administration of as needed medications.</p>				

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	<p>orders dated 4/23/15 that state, "Clonidine HCL 0.20 mg oral during dialysis prn . The order failed to evidence blood pressure parameters for the administration of the medication.</p> <p>On 9/29/15 at 1:30 PM, Employee D, Registered Nurse, did not have an accurately documented physician orders since there were no blood pressure parameters given for when this medication would be given.</p> <p>4. The agency policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" with a date of July 4, 2012 stated, "The patient's Plan of care will be guided and developed based on the Comprehensive Interdisciplinary Patient Assessment ... The comprehensive assessment interdisciplinary assessment must include the following ... current health status including co-morbid conditions ... blood pressure and fluid management needs ... The Plan of Care must include measurable and expected outcomes and an estimated timetable to achieve these outcomes."</p> <p>5. The agency policy titled "Physician Order Documentation" with a date of June 19. 2013 stated, "It is the nurse's responsibility to ensure that all ...</p>			

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V 0543 Bldg. 00	<p>medications or any care provided to the patient have an accurately documented physician order ... The nurse is obligated to verify any order which is otherwise unclear or questionable."</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 record review and interview, the facility failed to ensure it had provided the necessary care and services to manage the patient's fluid volume status in 1 (#1) of 7 incenter hemodialysis records reviewed and monitored the patient's blood pressures every 30 minutes for 3 of 7 incenter</p>	V 0543	<p>On 10-15-15 the Director of Operations reviewed with the Clinical Manager and by 10-30-15 the Clinical Manager will train all Registered Nurse (RN) and Patient Care Technician (PCT) staff on: ·FMS-CS-IC-I-110-125A Comprehensive Interdisciplinary Assessment and Plan of Care</p>	10/30/2015

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	<p>hemodialysis patients (#3, #4, and #6).</p> <p>The findings include:</p> <p>Regarding the management of the patient's fluid status:</p> <p>1. Clinical record #1 included physician orders dated 9/2/15 that identified the desired weight at the end of the treatment, the estimated dry weight (EDW), was 65.5 kilograms (kg). Hemodialysis treatment flow sheets evidenced the patient's weight was below the estimated dry weight at the start of the treatment and these EDWs had not been adjusted.</p> <p>A. A hemodialysis flow sheet dated 9/07/15 evidenced the patient's EDW was 64.8 kg at preweight at the beginning of treatment and 62.8 post weight at the end of treatment.</p> <p>B. A hemodialysis flow sheet dated 9/09/15 evidenced the patient's EDW was 60.2 kg at preweight at the beginning of treatment and 59.10 post weight at the end of treatment.</p> <p>C. A hemodialysis flow sheet dated 9/09/15 evidenced the patient's EDW was 60.2 kg at preweight at the beginning of treatment and 59.10 post weight at the</p>		<p>Policy</p> <ul style="list-style-type: none"> ·Dose of Dialysis: Provide necessary care and services to manage the patient's volume status ·FMS-CS-IC-II-150-033A: Physician Order Documentation Policy: <ul style="list-style-type: none"> ·Responsibility: It is the nurses' responsibility to ensure that all treatments, medications, labs or any care provided to the patient have an accurately documented physician order (inclusive of EDW) ·FMS-CS-IC-I-110-133A : Patient MonitoringDuring Patient Treatment Policy: <ul style="list-style-type: none"> ·Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently, as needed <p>The meeting agenda and attendance records will be available for review at the facility. By 10-30-15 all EDW will be reviewed and, with the MD, adjusted as indicated to maintain appropriate fluid volume status. Fluid management needs will be addressed as part of patients CIA/POC process as well. The Clinical Manager and or designee will perform Medical Record Audits for compliance according to the QAI Workflow Calendar, address identified issues, and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee</p>				

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	<p>end of treatment</p> <p>D. A hemodialysis flow sheet dated 9/11/15 evidenced the patient's EDW was 60.2 kg at preweight at the beginning of treatment and 59.10 post weight at the end of treatment.</p> <p>E. A hemodialysis flow sheet dated 9/14/15 evidenced the patient's EDW was 59.3 kg preweight at the beginning of treatment and 59 kg post weight at the end of treatment.</p> <p>F. A hemodialysis flow sheet dated 9/16/15 evidenced the patient's EDW was 59.7 kg preweight at the beginning of treatment and 58.5 kg post weight at the end of treatment.</p> <p>G. A hemodialysis flow sheet dated 9/18/15 evidenced the patient's EDW was 60.20 kg at preweight and 59.50 kg at post weight.</p> <p>H. A hemodialysis flow sheet dated 9/21/15 evidenced the patient's EDW was 61 kg prior to treatment and 59.5 kg at post weight.</p> <p>2. On 9/26/15 at 4:30 PM, Employee C, the clinic manager, and Employee D, Registered Nurse, indicated the EDW needed clarified with the physician.</p>		<p>investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure the facility provides the necessary care and services to manage patients' fluid volume status.</p>		

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	<p>Regarding blood pressures monitored every 30 minutes:</p> <p>3. Clinical record #3 included treatment sheets that failed to evidence the patient's blood pressure had been checked at least every 30 minutes.</p> <p style="padding-left: 40px;">a. The treatment sheet dated 9/1/15 with dialysis initiation at 6:50 AM and terminated at 11:20 AM evidenced the blood pressure was assessed at 9:05 AM and then not again until 11:20 AM.</p> <p style="padding-left: 40px;">b. On 9/29/15 at 12:55 PM, Employee A, the alternate administrator, indicated the blood pressure was not checked in a timely manner.</p> <p>4. Clinical record #4 included treatment sheets that failed to evidence the patient's blood pressure had been checked at least every 30 minutes.</p> <p style="padding-left: 40px;">a. The treatment sheet dated 9/8/15 with dialysis initiation at 11:54 AM and terminated at 3:01 PM evidenced the blood pressure was assessed at 1:31 PM and not again until 2:24 PM during the treatment time.</p>			

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	<p>b. On 9/29/15 at 1:10 PM, Employee A, the alternate administrator, indicated the blood pressure was not assessed every 30 minutes.</p> <p>5. Clinical record #6 included treatment sheets that failed to evidence the patient's vital signs including blood pressure had been checked at least every 30 minutes.</p> <p>a. The treatment sheet dated 9/14/15 with dialysis initiation at 10:47 AM and terminated at 1:35 PM evidenced the blood pressure was assessed at 10:48 AM and not again until 11:35 AM during the treatment time. Again, during this treatment, the blood pressure was assessed at 12:31 PM and next assessed at 1:13 PM.</p> <p>On 9/29/15 at 1:20 PM, Employee A, the alternate administrator, indicated the blood pressure was not assessed every 30 minutes.</p> <p>b. The treatment sheet dated 9/25/15 with dialysis initiation at 11:06 AM and terminated at 2:26 PM evidenced the blood pressure was assessed at 1:34 PM and not again until 2:28 PM during the treatment time.</p>			

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V 0544	<p>On 9/29/15 at 1:20 PM, Employee D, Registered Nurse, indicated the blood pressure was not assessed every 30 minutes.</p> <p>6. The policy titled "Physician Order Documentation" with a date of June 20, 2013 stated, "It is the nurse's responsibility to ensure that all treatments, medications, labs or any care provided to the patient have an accurately documented physician order."</p> <p>7. The policy titled "Patient Monitoring During Patient Treatment" with a date of August 20, 2014 stated, "Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed."</p> <p>494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE</p>				

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Bldg. 00	<p>Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.</p> <p>Based on record review and interview, the facility failed to ensure the blood flow rate on the prescription was followed for 4 of 7 incenter hemodialysis records (#1, 3, 4, and 7) reviewed.</p> <p>Findings include:</p> <p>1. Clinical record #1 included hemodialysis orders that identified the blood flow rate (BFR) was to be 400 milliliters per minute.</p> <p>A. The flow sheet dated 8/31/15 evidenced BFRs of 405 and 450 during the treatment with no explanation as to why the BFR was not followed.</p> <p>B. The flow sheet dated 9/02/15 evidenced BFRs of 300 and 450 during the treatment with no explanation as to why the BFR was not followed.</p> <p>C. The flow sheet dated 9/07/15 evidenced BFRs of 300 and 450 during the treatment with no explanation as to why the BFR was not followed.</p>	V 0544	<p>On 10-15-15 the Director of Operations reviewed with the Clinical Manager and by 10-30-15 the Clinical Manager will re-train all Registered Nurse (RN) and Patient Care Technician (PCT) staff on:</p> <ul style="list-style-type: none"> ·FMS-CS-IC-II-150-033A: Physician Order Documentation Policy: ·Responsibility:It is the nurses' responsibility to ensure that all treatments, medications, labs or any care provided to the patient have an accurately documented physician order (inclusive of BFR) ·FMS-CS-IC-I-110-133A: Patient Monitoring During Patient Treatment Policy: ·Blood flow rate: Check prescribed BFR is being achieved. Make adjustments as needed ·Inability to reach prescribed orders, report to RN/document justification as indicated <p>The meeting agenda and attendance records will be available for review at the facility. The Clinical Manager and or designee will perform Medical Record Audits for compliance according to the QAI Workflow Calendar, address identified</p>	10/30/2015	

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	<p>D. The flow sheet dated 9/09/15 evidenced BFRs of 445, 448, and 450 during the treatment with no explanation as to why the BFR was not followed.</p> <p>E. The flow sheet dated 9/11/15 evidenced BFRs of 450 during the treatment with no explanation as to why the BFR was not followed.</p> <p>F. The flow sheet dated 9/14/15 evidenced BFRs of 450 during the treatment with no explanation as to why the BFR was not followed.</p> <p>G. The flow sheet dated 9/16/15 evidenced BFRs of 440 and 450 during the treatment with no explanation as to why the BFR was not followed.</p> <p>H. The flow sheet dated 9/21/15 evidenced BFRs of 450 during the treatment with no explanation as to why the BFR was not followed.</p> <p>I. 9/26/15 at 4:30 PM, Employee C, the clinic manager, and Employee D Registered Nurse, indicated the physician orders were not followed.</p> <p>2. Clinical record #3 included hemodialysis orders that identified the BFR was to be 500 milliliters per minute.</p>		<p>issues, and report findings and actions taken at monthly QAI meetings. In the event of discrepancies or problematic outcomes, the Committee investigates to determine the root cause of the issue and develops, implements, and tracks a corrective action plan through to resolution of the issue at hand. The Clinical Manager is responsible and the QAI Committee monitors to ensure that the BFR on the prescription is followed.</p>		

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	<p>A. The flow sheet dated 9/15/15 evidenced BFRs of 450 and 453 during the treatment with no explanation as to why the BFR was not followed.</p> <p>B. On 9/29/15 at 12:55 PM, Employee A, the alternate administrator, indicated the physician's order was not followed.</p> <p>3. Clinical record #4 included hemodialysis orders that identified the BFR was to be 450 milliliters per minute.</p> <p>A. The flow sheet dated 9/12/15 evidenced BFRs of 349 and 350 during the treatment with no explanation as to why the BFR was not followed.</p> <p>On 9/29/15 at 1:06 PM, Employee A, alternate administrator, indicated the physician's order was not followed.</p> <p>B. The flow sheet dated 9/15/15 evidenced BFRs of 380 during the treatment with no explanation as to why the BFR was not followed.</p> <p>On 9/29/15 at 1:05 PM, Employee D, Registered Nurse, indicated the physician's order was not followed.</p> <p>C. The flow sheet dated 9/22/15</p>			

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	<p>evidenced BFRs of 300, 350, and 400 during the treatment with no explanation as to why the BFR was not followed.</p> <p>On 9/29/15 at 1:25 PM, Employee A, the alternate administrator, indicated the physician's order was not followed.</p> <p>4. Clinical record #7 included hemodialysis orders that identified the BFR was to be 250 milliliters per minute.</p> <p>A. The flow sheet dated 9/1/15 evidenced BFRs of 300, 305, 351, and 354 during the treatment with no explanation as to why the BFR was not followed.</p> <p>B. On 9/25/15 at 3:35 PM, Employee A, alternate administrator, indicated the physician's order was not followed.</p> <p>5. The policy titled "Patient Monitoring During Treatment" with a date of August 20, 2014 stated, "Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary ... blood flow rate: check prescribed blood flow is being achieved."</p>			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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