

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 012507	(X3) Date Survey Completed 03/14/2019
Name of Provider or Supplier Fresenius Kidney Care Mobile	Street Address, City, State 2620 Old Shell Road, Mobile, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies (Each deficiency should be preceded by full regulatory or LSC identifying information)
E0000	A recertification survey was conducted on 3/12/19 - 3/14/19. The facility was found to be in substantial compliance with the Conditions of Participation for Emergency Preparedness.
V0000	'CORE'
V0111	<p>IC-SANITARY ENVIRONMENT CFR(s): 494.30</p> <p>The dialysis facility must provide and 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>This STANDARD is not met as evidenced by: Based on observations, facility procedure and interview, it was determined the staff failed to follow their own policy for bleach preparation and storage. This had the potential to negatively affect all patients who dialyze at the facility. Findings include: Facility Procedure: Mixing Bleach FMS-CS-IC-II-155-110C5 Revision Date: 20-March-2013 ...Procedure: Follow the steps below for mixing bleach: 2...Measuring...1: 100=1 part bleach + (plus) 100 parts water...1:10=1 part bleach +10 parts water... 4. Label opaque container with "Bleach Solution", strength of solution.. 6 Discard solution daily... Observations of care were conducted on 3/12/19 at 7:45 AM. There were 5 plastic containers which contained clear solutions on the supply carts on both sides of the patient treatment area and on the counter next to the dirty sink in the back of the treatment area. There was no documentation of what solution was in the containers. In an interview on 3/12/19 at 8:00 AM, the surveyor asked Employee Identifier (EI) # 4, Certified Clinical Hemodialysis Technician, what was in the</p>

containers? EI # 4 reported bleach. The plastic bleach containers were not labeled with the contents and the containers were not labeled with the strength of bleach solution. EI # 4 confirmed the above findings.

V0113

IC-WEAR GLOVES/HAND HYGIENE
CFR(s): 494.30(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on observations, review of facility policy and procedure and interview, it was determined the facility failed to ensure all patients performed hand hygiene and washed the vascular access site and staff performed hand hygiene prior to IV (intravenous) medication administration and after cleaning the stethoscope. This affected PI (Patient Identifier) # 5, # 11, # 13 and # 12 had the potential to negatively affect all patients who dialyze at the facility. Findings include: Facility Policy: Hand Hygiene Document Number: FMS-CS-IC-II-155-090A Effective Date: 20-MAR-2013 ...The purpose of this policy is to prevent transmission of pathogenic microorganisms to patients and staff through cross contamination. ...Hand Hygiene Hands will be... decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water... Before and after direct contact with patients Entering and leaving the treatment area Before performing any invasive procedure such as vascular access cannulation or administration of parental medications ...After contact with inanimate objects near the patient... Patients should perform hand hygiene if able, prior to and after each dialysis treatment. As needed, direct patient care staff will...explain risk of contamination with regard to their vascular assess and hands to all patients.... Facility Procedure: Access Assessment and Cannulation Document Number: FMS-CS-IC-I-115-014C Effective Date: 22-AUG-2018 ...Assessment of Vascular Access Step 1. Prior to treatment, ask your patient to wash access area with liquid soap and water for one minute. Dry with clean paper towel. Wash access...if patient's unable to clean their access... Policy: Cleaning and Disinfection of the Stethoscope Policy Number: FMC-CS-IC-II-155-123C Date Revised: 04-Jan-2012 Procedure: Step: 1. Clean hands with alcohol based hand sanitizer. 2. While the alcohol product still on hands, rub the diaphragm of stethoscopes with hands until the entire diaphragm surface covered with the alcohol product. 3. Complete hand hygiene.... An observation was conducted on 3/12/19 at 10:30 AM to observe care provided. During the observation, Employee Identifier (EI) # 7, Registered Nurse (RN), completed the post assessment of the patient at station 24. Once complete, EI # 7 obtained hand sanitizer and rubbed the diaphragm of the stethoscope. EI # 7 failed to obtain additional hand sanitizer and sanitize hands after equipment cleaning. An interview was conducted on 3/14/19 at 11:15 AM with EI # 1, Clinic Manager and EI # 2, Director of Operations, who confirmed the policy was not followed for hand hygiene. 30952 At 10:33 AM, Employee Identifier (EI) # 5, Registered Nurse, entered station 6, gloved, with a syringe in hand, then laid the syringe on the chairside table. EI # 5 assessed PI # 5 with the stethoscope, lifted PI # 5's pant legs and placed his/her gloved hands on the ankles and feet during patient assessment. With the same gloves, EI # 5 retrieved the syringe from the chairside table and administered IV medication. EI # 5 failed to remove gloves, perform hand hygiene and don clean gloves after direct patient contact and before IV medication administration. On 3/12/19 at 12:45 PM, PI # 11 entered the patient treatment area, then to the scales with EI # 6, Patient Care Technician. EI # 6

accompanied PI # 11 to station 3. PI # 11 failed to perform hand hygiene and wash the vascular access site upon entering the treatment area. After PI # 11 sat down at station 3, the surveyor observed PI # 11 with clear plastic wrap around the left arm access site. EI # 6 cleaned the access site with 70 % Isopropyl Alcohol prep pads. EI # 6 failed to encourage the patient to perform hand hygiene and the access site was not washed with soap and water prior to cannulation as directed per policy. At 12:55 PM, EI # 5 entered station 7 with a syringe in gloved hand laid the syringe on the chairside table. EI # 5 assessed PI # 13 with the stethoscope, then placed gloved hands on lower legs and feet. With the same gloves, EI # 5 administered IV medication. EI # 5 failed to remove gloves, perform hand hygiene and don clean gloves after patient contact and prior to IV medication administration. At 1:00 PM, PI # 12 entered the patient treatment area, weighed at the scales and sat down at station # 4. PI # 12 failed to perform hand hygiene and wash the vascular access site upon entering the treatment area. EI # 6 cleaned the access site with 70 % Isopropyl Alcohol prep pads and cannulated the access. Following treatment initiation, the surveyor interviewed PI # 12 who confirmed no hand hygiene and vascular access washing was performed upon entering the treatment area. At 1:05 PM, EI # 5 entered station 3 with a syringe in gloved hand and laid the syringe on the chairside table. EI # 5 assessed PI # 11 with a stethoscope, then assessed the lower legs and feet. Wearing the same gloves, EI # 5 administered the IV medication from the syringe. EI # 5 failed to remove gloves, perform hand hygiene and don clean gloves prior to administering IV medication as directed per the facility policy. In an interview on 3/14/19 at 10:45 AM, EI # 2, Director of Operations, confirmed staff failed to follow infection control procedures.

V0403

PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU
CFR(s): 494.60(b)

The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

This STANDARD is not met as evidenced by:
Based on review of facility procedure, facility Equipment Records documentation, and interviews with facility staff, it was determined the facility staff failed to ensure accurate records were kept for dialysis machine hours for preventive maintenance (PM) for 3 of 5 hemodialysis (HD) machines reviewed. This had the potential to negatively affect all patients who dialyze at this facility. Findings include: Facility Procedure: 2008T Preventive Maintenance Procedures Revision G 1.0 Introduction Preventive Maintenance for the 2008T Hemodialysis System is simple and straightforward... Maintenance is performed in only two intervals: six (6) months, and annually or after 4000 hours of operation... An interview was conducted on 3/13/19 at 1:15 PM with Employee Identifier (EI) # 8, Biomedical Technician who verified the facility was utilizing Fresenius 2008T hemodialysis machines which require annual and semi-annual preventive maintenance (PM) or after 4000 hours of operation. Review of the Equipment Records for HD machine # 11 (Serial # 7TOS-202471) revealed an annual PM was completed on 4/29/18. There was no documentation of the machine clock hours (operating hours). Review of the Equipment Records for HD machine # 23 (Serial # 7TOS-203366) revealed a semi annual PM was completed on 4/29/18. There was no documentation of the machine clock hours (operating hours). Review of the Equipment Records for HD machine # 24 (Serial # 7TOS-203393) revealed a semi annual PM was completed on 4/29/18. There was no documentation

of the machine clock hours (operating hours). An interview was conducted on 3/14/19 at 11:50 AM with EI # 9, Regional Technical Program Manager, who confirmed operating hours must be documented with all PM and verified the aforementioned findings.

V0544

POC-ACHIEVE ADEQUATE CLEARANCE

CFR(s): 494.90(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of medical records (MR), the facility's policy and procedures and interview with facility staff, it was determined the facility failed to ensure the staff followed the physician's order for the Dialysate Flow Rate (DFR). This affected 1 of 10 records reviewed including Patient Identifier (PI) # 10 and had the potential to negatively affect all patients served by the facility. Findings include: Facility Policy: Auto Flow Dialysate Policy Document Number: FMS-CS-IC-105-017A Revision Date: 04-APR-2012 Purpose: The purpose of this policy is to provide guidance on the use of the auto flow dialysate option. Overview: ...The Auto Flow feature allows for automatic optional dialysate flows proportionate to the blood flow rate. The Auto Flow Option automatically adjusts the dialysate flow at either 1.5 times the blood flow... or 2.0 times the blood flow ... with a maximum dialysate flow rate of 800 ml (milliliters) / min (minute). There are two Auto Flow selections: Option 1- selects the minimum dialysate flow rate during dialysis when Auto Flow is selected to either 300 or 500. (500 is the default selection) Auto Flow Rate: Blood Flow Rate (BFR) using Auto Flow 1.5: 316 - 415 Blood Flow Rate equals 500 Minimum Dialysate Rate. 1. PI # 10 transferred to the facility from a sister clinic on 2/7/19 with diagnoses including End Stage Renal Disease. Review of the physician orders dated 1/11/19 and 3/7/19 revealed orders for BFR 350, DFR autoflow 1.5. Record review for 6 treatment sheets between 2/7/19 to 3/9/19 revealed the treatment sheets dated 2/7/19, 2/9/19, 2/12/19 and 3/7/19 had the incorrect DFR of 600. An interview was conducted on 3/14/19 at 9:15 AM with Employee Identifiers (EI) # 1, Clinic Manager, and EI # 2, Director of Operations, who confirmed the documented DFR should have been 500.