

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)
V0403	<p>PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU CFR(s): 494.60(b)</p> <p>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.</p> <p>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</p>

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.