

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>012515</p>	<p><b>(X3) Date Survey Completed</b></p> <p>04/20/2023</p>
<p><b>Name of Provider or Supplier</b></p> <p>Fresenius Medical Care Opelika</p>	<p><b>Street Address, City, State</b></p> <p>2609 Village Professional Drive, Suite 2, Opelika, AL</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p><b>(X4) ID Prefix Tag</b></p>	<p><b>Summary Statement of Deficiencies</b></p> <p>(Each deficiency should be preceded by full regulatory or LSC identifying information)</p>
<p><b>V0403</b></p>	<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 observations, manufacturer's directions for use for Minncare HD (hemodialysis) Residual Test Strips, and staff interviews, it was determined the facility failed to ensure: 1. Minncare HD Residual Test Strips located in the water room and available for use were not expired. 2. Supplies located in the Home Hemodialysis (HHD) and the Home Peritoneal Dialysis (HPD) rooms and available for use were not expired. Findings include: Mar Cor Publication A Cantel Medical Company Date: 2016 Minncare HD Test Strips Minncare HD test strips provide quick results with easy-to-read indicators with the assurance of accurate results associated with a 510 medical device. Use the Minncare HD ...Test strips as a pass/fail measurement for adequate concentration of sterilant after dilution... Both Minncare HD 1% Indicator Test Strips and Minncare HD Residual Test Strips may be used up to and including the last day of the month indicated by the expiration printed on the container... A tour of the water treatment room was conducted on 4/18/23 at 8:15 AM. A single opened vial of Minncare HD Residual Test Strips was observed available for use with an expiration date of 2/15/23. Employee Identifier (EI) # 13, Administrative Assistant, was present during the tour and confirmed the test strips were expired. 40119 2. A tour was conducted on 4/18/23 at 10:50 AM of the HPD storage room. The following supplies were expired and available for patient use: a. 141 Green topped blood collection tubes with the expiration date of 12/31/22. b. 21 Lime green</p>

topped blood collection tubes with the expiration date of 1/31/23. c. 65 Safety lancets 21 Gauge (G) with the expiration date of 11/23/22. d. 55 Safety-Lok 1 ml (milliliter) 25 G syringes with the expiration date of 10/19. e. One NxStage (Home HD machine brand) conductivity preventive maintenance kit with the expiration date of 5/8/19. f. One Intravenous (IV) administration set with the expiration date of 8/7/22. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1, Director of Operations, who confirmed the supplies were expired and should not be available for patient use.

3. A tour was conducted on 4/18/23 at 11:39 AM of the HHD room. The following supplies were expired and available for patient use: a. One sterile 2 x 2 (two by two) gauze with the expiration date of 10/22. b. Four sterile 2 x 2 gauze with the expiration date of 11/22. c. Two sterile 2 x 2 gauze with the expiration date of 2/23. d. 23 RPC (brand of testing supplies) E-Z (easy) Check Blood Leak test strips with the expiration date of 1/31/19. e. One express fluid warmer disposable set with the expiration of 11/8/22. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1 who confirmed the supplies were expired and should not be available for patient use.

4. A tour was conducted on 4/20/23 at 12:50 PM of the HPD room. The following supplies were expired and available for patient use: a. 14 yellow topped blood collection tubes with the expiration date of 2/28/23. b. 17 red topped blood collection tubes with the expiration date of 2/8/23. c. 20 Stay safe cap PD connectology system with the expiration date of 1/31/23. d. 1 Exsept Plus (wound cleanser) 500 ml opened on 9/30/22 with an expiration date of 3/30/23. e. 2 sterile 2 x 2 gauze with the expiration date of 6/21. f. 2 sterile 2 x 2 gauze with the expiration date of 11/22. g. 39 Island 4 x 4 (four by four) dressings with the expiration date of 11/14/22. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1 who confirmed the supplies were expired and should not be available for patient use.