

<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>08/06/2025</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>V0000</b></p>	<p>An abbreviated onsite survey was conducted on 8/5/25 to 8/6/25 at Fresenius Medical Care Opelika to investigate complaint AL00051741. The facility consists of thirty incenter hemodialysis stations, which includes one isolation station. There is one home hemodialysis training and support station, and one home peritoneal dialysis training and support room. A Condition level deficiency was cited at Condition for Coverage (Cfc) 494.30, Infection Control, and related standards.</p>
<p><b>V0110</b></p>	<p>CFC-INFECTION CONTROL CFR(s): 494.30</p> <p>This CONDITION is not met as evidenced by: Based on observations, facility policy and procedure, and interviews, it was determined the facility failed to ensure the staff followed infection control requirements per regulations and facility policy and procedure. Refer to: V 111, and V 122.</p>
<p><b>V0111</b></p>	<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 and interviews, it was determined the facility failed to maintain and ensure a safe and sanitary environment for patients, staff, and visitors, which</p>

included: 1. The incenter patient treatment floor was free of pests/vermin. 2. The hand washing sink at the incenter medication preparation (med prep) counter was clean. 3. Incenter hemodialysis patient treatment chairs were in good repair without tears in the vinyl. The failure to maintain patient treatment chairs without tears was cited during the recertification survey conducted on 4/20/23. 4. The incenter treatment supply carts were clean. 5. The incenter treatment floors were without dirt/dust, and other brown /black substance build up. The failures increased the potential for contamination with blood and pathogenic microorganisms and had the potential to negatively affect all one hundred thirty-two patients who dialyze and receive home therapy services, facility staff, and visitors. Findings include: Observations were conducted on 8/5/25 from 11:15 AM to 5:20 PM. 1. On 8/5/25 from 4:35 PM to 5:20 PM a tour of the incenter (IC) treatment floor was conducted with Employee Identifier (EI) # 1 Clinical Manager (CM). EI # 1 picked up a piece of dialysis counter strip off the treatment floor at dialysis station twenty-seven. There was a black bug underneath the counter piece. The failure to ensure the facility was free from pests/vermin increases the risk of transmission of infectious disease. 2. The hand washing/clean sink at the med prep counter had pink/red substances surrounding the faucet plate, and rust along the sink bowl edge. This failure had the potential for contamination of intravenous and oral medications preparation and administration to all patients. 3. Thirteen of thirty IC hemodialysis dialysis treatment chairs had tears in the vinyl covering at the armrests, the bottom and middle seat cushions, and middle and lower footrests. Some chairs had multiple tears in different locations of the treatment chair. This failure prevented the patient treatment chairs from being properly disinfected between patient dialysis treatments, and increased the potential for contamination with blood and pathogenic microorganisms, including hepatitis B. 4. The four supply carts on the incenter treatment floor that contained patient treatment supplies had dirt, dust, cardboard pieces, and white substances along the cart sides and on the cart shelves. There was paper tape along inside and outside surfaces of the carts, including the cart handle. There was an open tape roll attached to one cart handle. There was a supply cart that held a box of clean clamps, and a thermometer. The cart shelf had four large, rusted bolts on the top shelf adjacent to the supplies. The treatment supply carts needed cleaning. The failure to maintain clean treatment supply carts increased the potential for contamination of supplies used to provide dialysis treatments. 5. There was dirt, an unidentified black substance, and dust build up along the IC treatment floors, including areas surrounding the hemodialysis machine, the dialysis stations, the emergency cart, and the patient scales. An interview was conducted on 8/5/25 at 5:20 PM with EI # 1, who confirmed the facility was not maintained in a safe and sanitary manner, which increased the potential for transmission of infectious organisms to patients, staff, and visitors.

**V0122**

**IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL**  
 CFR(s): 494.30(a)(4)(ii)

[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-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

This STANDARD is not met as evidenced by:  
 Based on observations, review of facility policy and procedure, and interviews, it was determined the facility failed to ensure: 1. Staff cleaned and disinfected dialysis stations which affected three of three observations for cleaning and disinfection of the

dialysis station during the survey. 2. Staff removed tape and tape residue from dialysis treatment chairs, which affected fifteen of thirty dialysis incenter (IC) hemodialysis (HD) stations. Failure to clean and disinfect the dialysis station between patient treatments was cited during the recertification survey conducted on 4/20/23. This has the potential to negatively affect one hundred two IC HD patients who dialyze at the facility, staff, and visitors. Findings include: Facility Policy and Procedure: Cleaning and Disinfecting of the Dialysis Station Published: 09/05/2023 Version: 14 Purpose ... of this policy is to provide guidelines to prevent the spread of disease...maintain a clean...safe...environment for patients, staff, and visitors. Background ...The nature of dialysis treatments with frequent exposure to blood...close proximity... immunocompromised status of dialysis patients makes dialysis a high-risk area for spreading infectious disease... Definition Dialysis Station...including dialysis machine, chair...and other reusable equipment...utilized during dialysis treatment...not limited to the following: ...IV) intravenous pole), BP (blood pressure) cuff...television... Dialysis Wall Box...connect central distribution systems to a HD machine...located in the chase wall behind the machine. General Cleaning ...After use...supplies brought to the dialysis station... (ex [example] Stethoscope) must be disinfected... Cleaning of the Dialysis Wall Boxes...and the area around the wall box must be routinely cleaned at the end of each treatment day...All surfaces shall be disinfected with 1:100 (one part bleach, 100 parts water) bleach solution. Special attention should be given to removing build-up and/or cleaning splatter and spray of concentrate solution.... Procedure Follow the steps below to disinfect the dialysis station after each dialysis treatment: ...3. Use a cloth wetted with 1:100...bleach solution...to clean and disinfect the dialysis station...machine, IV pole, B/P cuff...chaise wall behind chair... 4. Clean all surfaces... 5...While wiping...wipe all surfaces of the machine... 7. Surface disinfect dialysis wall box and the area/wall around the wall box at the end of each treatment day... 1. An observation was conducted on 8/5/25 at 3:25 PM at station 4 to observe EI (Employee Identifier) # 5, Certified Clinical Hemodialysis Technician, perform cleaning and disinfection of the dialysis station at the end of the treatment day. EI # 5 failed to disinfect the top section of the IV (intravenous) pole including the four IV hooks, and stethoscope hanging on a hook. and failed to disinfect the blood pressure cuff and wire basket on the HD side. EI # 5 failed to clean the television, and arm, and the counters surrounding the dialysis station. EI # 5 failed to disinfect the chaise wall cabinet and dialysis wall box per policy. An interview was conducted on 8/6/25 at 1:30 PM with EI # 1, Clinical Manager, who confirmed the staff failed to follow the facility policy for cleaning and disinfection of the dialysis station. 2. An observation was conducted on 8/5/25 at 3:35 PM for cleaning and disinfection of station 21. EI # 6, Patient Care Technician (PCT), failed to disinfect the top section of the IV pole and the four IV hooks. EI # 6 failed to clean the television, the television arm, the surrounding counters, the wall box, and chaise wall cabinet after the last treatment of the day. An interview was conducted on 8/6/25 at 1:30 PM with EI # 1, who confirmed the staff failed to follow the facility policy for cleaning and disinfection of the dialysis station. 3. An observation was conducted on 8/5/25 at 3:55 PM for cleaning and disinfection of station 8. EI # 7, PCT, failed to disinfect the top section of the IV pole and the four IV hooks, the television, television arm, the surrounding counters, the chase wall cabinet, and wall box after the last treatment of the day. An interview was conducted on 8/6/25 at 1:30 PM with EI # 1, who confirmed the staff failed to follow the facility policy for cleaning and disinfection of the dialysis station. 4. Observations were conducted on the treatment floor on 8/5/25 from 4:35 PM to 5:20 PM with EI # 1, Clinical Manager. Fifteen of thirty dialysis stations had paper tape and tape residue on the patient treatment chairs, tabletops, and counters surrounding the dialysis stations. There was dust and dirt build up on the counters surrounding the dialysis stations, especially around the television arm connections.

There was acid build up in the wall box at station 10. An interview was conducted on 8/5/25 at 5:20 PM with EI # 1 who confirmed staff had failed to ensure the dialysis stations were properly cleaned and disinfected between treatments. EI # 1 confirmed tape and tape residue not removed from the station could potentially lead to transmission of bloodborne pathogens, such as hepatitis B virus and other infections, from one patient to another in a HD unit.

**V0401**

**PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT**  
CFR(s): 494.60

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.

This STANDARD is not met as evidenced by:  
Based on observations, and interviews with incenter (IC) hemodialysis (HD) patients and staff, it was determined the facility failed to ensure the IC dialysis treatment chairs were maintained to ensure patients dialyzed in a comfortable environment. This affected Patient Identifier (PI) # 3, PI # 4, PI # 5, PI # 6, had the potential to negatively affect the one hundred two IC HD patients who dialyze at the facility. Findings include: 1. Observations were conducted on 8/5/25 and revealed four of thirty IC HD patient treatment chairs cushions had outlines in the seat and mid back areas, cushions sagged, and were uneven, which revealed the cushions were worn, and not in good repair. Random interviews were conducted with IC HD patients on 8/5/25 and 8/6/25. Four patients, PI # 3, PI # 4, PI # 5, PI # 6, reported the dialysis treatment chairs were not comfortable, had tears in the vinyl, and some chairs had worn out seat and mid back cushions, which were uncomfortable. An interview was conducted on 8/5/25 at 5:20 PM with Employee Identifier # 1, Clinical Manager, who confirmed the treatment chairs had excessive wear, and reported ten patients' treatment chairs ordered one year ago were not received. The facility failed to ensure the treatment environment was maintained for comfort and patient safety during dialysis treatments.

**V0402**

**PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY**  
CFR(s): 494.60(a)

The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public.

This STANDARD is not met as evidenced by:  
Based on observations, facility Quality Improvement documentation, and interviews, it was determined the facility failed to maintain the integrity of the dialysis station countertops, and ensure all light sources were covered. This affected the one hundred two incenter hemodialysis patients who dialyze at the facility and staff. Findings include: Observations were conducted on the incenter (IC) treatment floor on 8/6/25 from 4:35 PM to 5:20 PM and revealed multiple countertops surrounding the dialysis stations were not intact, and free from damage. The lack of an intact surface integrity prevents effective cleaning of the dialysis station and increases the potential for microbial growth on the counter surface. An observation was conducted at the IC treatment floor medication preparation sink on 8/5/25 at 4:45 PM. The light fixture cover over the hand washing sink was lying on the counter, and not secured on the fixture, which was a safety concern. Employee Identifier (EI) # 1, Clinical Manager,

present during the observations, was interviewed on 8/5/25 at 5:20 PM. EI # 1 confirmed the countertops were in disrepair, and in need of repair/replacement, and the cover was not secured to the light fixture. A review of the June 2025 Quality Improvement documentation revealed the "Physical Environment Building Inspection, Interior Physical Environmental Inspection audit score was 72.73". There was no documentation the facility identified the dialysis station counters and light fixtures in need of repairs and no documentation a plan had been put in place to make needed facility repairs. An interview was conducted on 8/6/25 at 11:15 AM with EI # 1 who confirmed the facility had failed to ensure the dialysis station counter surfaces integrity was maintained for patient and staff safety, and light fixtures had covers.

**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 observations, review of patient Treatment Sheet (TS) documentation, and interview, it was determined the facility failed to ensure the dialysate flow rate (DFR) and blood flow rate (BFR) orders were followed. This affected one of five dialysate prescription verifications conducted, and included Patient Identifier (PI) # 1, and one of four TS reviews for early termination, and included PI # 2. Failure to delivery BFR and DFR according to physician orders was cited during the recertification survey conducted on 4/20/23. This failure to follow the dialysis prescription for DFR and BFR had the potential for problem meeting adequacy goals and could negatively affect the one hundred two incenter (IC) patients who dialyze at the facility. Findings include: 1. Dialysis prescription verifications conducted on 8/5/25 at 11:45 AM at station two with Employee Identifier (EI) # 3, Registered Nurse, revealed PI # 1's ordered DFR was 800 and the current DFR delivery was 500. EI # 3 confirmed staff had failed to follow the physician orders for DFR. 2. Observations of care were conducted on 8/5/25 from 4:05 PM to 4:50 PM and revealed four patients had remaining dialysis treatment time and the treatments were discontinued before completion, which included PI # 2. Review of PI # 2 's TS dated 8/5/25 revealed the ordered BFR was 400 and DFR was 2.0 (800). Further review of the 8/5/25 TS revealed the BFR was 350 and DFR 700 the entire three-hour twelve-minute treatment. An interview was conducted on 8/7/25 at 1:30 PM with EI # 1, Clinical Manager, who confirmed the staff failed to follow physician order for BFR/DFR delivery.