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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>852587             | <b>(X3) Date Survey Completed</b><br><br>02/07/2025 |
| <b>Name of Provider or Supplier</b><br><br>Fresenius Kidney Care Richmond County   | <b>Street Address, City, State</b><br><br>2556 Tobacco Road Suite A, Hephzibah, GA |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b><br><br>(Each deficiency should be preceded by full regulatory or LSC identifying information)  |
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| <b>V0547</b>              | <p>POC-MANAGE ANEMIA/H/H MEASURED Q MO<br/>CFR(s): 494.90(a)(4)</p> <p>The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of facility records and staff interview, it was determined that the interdisciplinary team (IDT) failed to investigate, develop, and implement a plan of care for patient's unique anemia management needs in order to attain and maintain appropriate blood levels of Hemoglobin (Hgb - protein in red blood cells that carries oxygen), for one of one sampled patient (P#1), whose Hgb levels were below 10 g/dL (grams per deciliter) and continued to drastically drop or trended down from November 14, 2024 through January 28, 2025 (last Hgb result). Normal hemoglobin is 12-14 g/dL, with 10 g/dL being considered low for dialysis patients. Severe anemia in dialysis patients, like a Hgb of 6.0 g/dL, can lead to significant consequences including: extreme fatigue, reduced exercise tolerance, shortness of breath, increase risk of heart failure, left ventricular hypertrophy, poorer quality of life, higher mortality rate, and increased risk of cardiovascular events due to the body's struggle to deliver adequate oxygen to the tissues, potentially worsening their already compromised kidney function. Findings Include: A review of P#1's Hgb lab values, anemia management reports, and P#1's care plan revealed that her Hgb levels were below 10 g/dL and drastically trended down between November 14, 2024 through January 28, 2025 (last Hgb result). - On 11/14/24 - Hgb = 8.8 - On 11/21/24 Hgb = 8.2 - On 12/03/24- Hgb = 8.0 - On 12/12/24- Hgb = 8.7 - On 12/19/24 - Hgb = 8.0 - On 1/28/25 - Hgb = 6.0 A review of the facility's Mircera (a long-acting erythropoiesis-stimulating agent, [ESA], used for the treatment of anemia associated</p> |

with chronic kidney disease) Algorithm In-Center 4.0, stated: Exception Criteria: Rapid Hgb Fall: Hgb falling greater than 1.0 g/dL over two weeks and dose not currently on hold - increase dose using column 1 of the Maintenance Dose Chart (Applicable only to patients receiving Mircerca, not patients on hold). Hgb less than 8.0 g/dL: Consult Provider for orders. - A review of the "Providers Rounding Notes" dated 11/24/2024, revealed that: - On 8/27/24, P#1 received Mircerca 30 micrograms (mcg) and on 9/19/24 P#1 received another dose of Mircerca 30 mcg. - On this same "Providers Rounding Notes", dated 11/24/24, the Physician Assistant (PA AA) stated under "Anemia Assessment": Jehovah's Witness - does not accept blood products. Continue Anemia protocol but hold ESA until she gets clearance from OB/GYN (Obstetrician/Gynecologist) regarding potential adnexal mass (a growth or lump found in the female reproductive organs known as the adnexa) (sic). The appointment date to see OB/GYN: April 17, 2025. A review of facility records on 2/6/25 revealed no documented IDT progress notes of P#1 from 11/14/24 to 1/28/25. - P#1 was hospitalized on 1/3/25 with a diagnosis of fluid overload. - P#1 was hospitalized on 1/6/25 with a diagnosis of Right Pleural Effusion. Per hospital's H&P (History and Physical), it stated, "Epogen was increased to 20,000 units three times weekly". - P#1 was hospitalized again on 2/4/25 with shortness of breath (SOB). A review of P#1's "Treatment Sheet for Facility..." from 1/28/25 through 2/3/25 revealed no documented dose of Mircerca or Epogen given during dialysis treatment. There was no documentary evidence that the nephrologist or medical director were notified of the above information regarding P#1's continued drop in the Hbg count or that P#1 was not receiving ESA. - On 2/5/25 Mircerca 30 mcg was given after P#1's last hospitalization on 2/4/25. A review of P#1's Plan of Care dated 3/29/24 and was last updated by a Registered Nurse on 4/3/24, stated: - P#1's status was stable. Goal -Hgb 10-11g/dL. Goal due 7/28/2024. There were no new goals documented. Change ESA dose (per MD order/per algorithm). There was no new Plan of Care initiated by the IDT relative to P#1's worsening anemia. - During a discussion with the Facility Administrator on 2/5/25 at 3:00 p.m, she stated that P#1 is a Jehovah's Witness and refuses to take Epogen or Mircerca. - A review of P#1's chart between 11/4/24 through 1/28/25, revealed no patient education regarding risk and benefits of Epogen or Mircerca (ESA), and there was no documentary evidence that P#1 refused the Epogen or Mircerca. - During a follow-up discussion with the Facility Administrator on 2/6/25 at 10:00 a.m., the Facility administrator was asked if she was aware of P#1's ESA being put on hold until April 17, 2025, after her appointment with OB/GYN, and P#1's current Hgb was 6.0g/dL. The Facility Administrator stated that P#1 just got out of the hospital and she was on Mircerca 30 mcg every two weeks. - On 2/7/25 at 11:00 a.m., the Facility Administrator acknowledged the above findings and stated that P#1 should have been deemed unstable.