Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 012515	(X3) Date Survey Completed 04/20/2023
Name of Provider or Supplier Fresenius Medical Care Opelika	Street Address, City, State 2609 Village Professional Drive, Suite 2, Opelika, 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)
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, facility policies, and interviews, it was determined the facility failed to ensure: 1. The staff followed the physician's orders for Blood Flow Rate (BFR) and/or Dialysate Flow Rate (DFR). 2. The patient documented the number and amount of exchanges on the PD (Peritoneal Dialysis) treatment record. This affected six of seven in-center hemodialysis records reviewed including Patient Identifier (PI) # 8, PI # 9, PI # 10, PI # 2, PI # 1, PI # 3, and one of two home PD records reviewed, including PI # 7. This had the potential to negatively affect all patients dialyzing at the facility. Findings include: Facility Policy: Patient Assessment and Monitoring Published: 09/29/18 Version: 3 Monitoring During Treatment 3. Machine Parameters and Extracorporeal Circuit Check machine settings and measurements Check prescribed blood flow is being achieved or reason is documented in medical record ... Check dialysate flow rate setting is correct, and the prescribed flow is being delivered ... 4. Document any findings and interventions in the medical record. Facility Policy: Home Therapies Patient Treatment Record Keeping Published: 11/2/2020 Version: 1 Purpose: The purpose of this policy is to provide guidance for documentation of dialysis treatments for home dialysis patients. Background: The treatment flowsheet is used to monitor patient...aspects of treatment...and compliance with treatment regimen... Policy: A record is required for each dialysis treatment. Patients and/or patient care partners will be taught to complete a daily record of home dialysis treatments and...educated regarding the

importance of maintaining the records completely and accurately. ...Home treatment records will be reviewed by the home therapy registered nurse during patient monthly clinic visits to identify trends, errors or omissions, and other issues or concerns to be addressed with the patient and/or care partner... 1. PI # 8 was admitted to the facility on 9/14/2020 with diagnoses including End Stage Renal Disease (ESRD). Review of the Order Summary Report (OSR) revealed Hemodialysis (HD) orders dated 3/27/23 which included BFR 400 and DFR Autoflow 1.5 (600). Review of the Treatment Sheet (TS) dated 4/5/23 revealed the BFR was decreased to 300 from 10:31 AM to 11:30 AM and from 11:59 AM to 1:56 PM. There was no reason documented why the BFR was 300 and not 400 as ordered. Review of the TS dated 4/17/23 revealed the DFR was 800 the entire treatment from 10:20 AM to 2:14 PM. There was no reason documented why the DFR was 800 and not 600 as ordered. An interview was conducted on 4/19/23 at 11:27 AM with Employee Identifier (EI) # 2, Director of Operations (DO), Sister Facility, who verified the staff failed to document the reason the BFR was not delivered as ordered and failed to administer the DFR per physician orders. 2. PI # 9 was admitted to the facility on 5/3/22 with diagnoses including ESRD. Review of the OSR revealed HD orders dated 2/9/23 which included BFR 450 and DFR Autoflow 1.5 (700). Review of the TS dated 4/6/23 revealed the BFR was 400 and DFR was 600 the entire treatment from 5:34 AM to 9:52 AM. There was no reason documented why the BFR was 400 and not 450 as ordered and the DFR was 600 and not 700 as ordered. Review of the TS dated 4/8/23 revealed the treatment was initiated at 5:40 AM and there was no documentation of BFR and DFR until 6:01 AM. The staff failed to administer the BFR 450 and DFR 700 per the physician's order upon initiation of treatment at 5:40 AM. Further review of the TS dated 4/8/23 revealed the BFR was 400 from 6:01 AM to 8:11 AM, then the BFR was decreased to 170 and the DFR decreased to 140 from 8:11 AM to 8:31 AM, at which time the BFR was increased to 400 until the end of treatment at 10:09 AM. There was no reason documented why the BFR was 170 and 400 and not 450 as ordered and the DFR was 140 and not 700 as ordered. Review of TS dated 4/11/23 revealed the BFR was 400 from 5:45 AM to 6:00 AM and from 6:34 AM until the end of treatment at 10:33 AM. The DFR was at 800 the entire treatment from 5:45 AM until 10:33 AM. There was no reason documented why the BFR was 400 and not 450 as ordered and the DFR was 800 and not 700 as ordered. Review of TS dated 4/13/23 revealed the DFR was 800 the entire treatment from 5:48 AM until 10:18 AM. There was no reason documented why the DFR was 800 and not 700 as ordered. Review of TS dated 4/15/23 revealed the DFR was 800 the entire treatment from 5:38 AM until 10:13 AM. There was no reason documented why the DFR was 800 and not 700 as ordered. Review of the TS dated 4/18/23 revealed the treatment was initiated at 5:40 AM with a DFR of 500. At 6:05 AM, the DFR was increased to 800. At 6:38 AM, the DFR was decreased to 500, and then from 7:01 AM until 8:00 AM, the DFR was increased to 800, at which time the DFR was decreased to 500 until 8:41 AM. There was no reason documented why the DFR was 500 and 800 and not 700 as ordered. An interview was conducted on 4/19/23 at 3:15 PM with EI # 2, who verified the staff failed to document the reason the BFR was not delivered as ordered and failed to administer the DFR per physician orders. 3. PI # 10 was admitted to the facility on 8/6/2020 with diagnoses including ESRD. Review of the OSR revealed HD orders dated 1/26/23 which included BFR 400 and DFR Manual 500. Review of the TS dated 4/11/23 revealed the DFR was increased to 800 from 10:32 AM to 11:30 AM. There was no reason documented why the DFR was 800 and not 500 as ordered. Review of the TS dated 4/13/23 revealed the DFR was 800 the entire treatment from 10:06 AM to 2:08 PM and the BFR was decreased to 300 from 12:41 PM to 2:08 PM. There was no reason documented why the DFR was 800 and not 500 as ordered and the BFR was 300 and not 400 as ordered. An interview was conducted on 4/19/23 at 2:45 PM with

EI # 2, who verified the staff failed to document the reason the BFR was not delivered as ordered and failed to administer the DFR per physician orders. 41624 4. PI # 2 was admitted to the facility on 1/6/23 with a diagnosis of ESRD. Review of the OSR revealed HD orders dated 2/24/23 which included BFR 400. Review of the TS dated 4/14/23 revealed the BFR was decreased to 350 from 1:32 PM to end of treatment at 2:43 PM. There was no documentation why the BFR was not at the ordered rate of 400. Review of the TS dated 4/17/23 revealed the BFR was 350 at start of treatment 10:40 AM to 11:02 AM, and from 12:02 PM to 1:31 PM the BFR was 350. Further review of the 4/17/23 TS revealed from 1:31 PM to 2:03 PM the BFR was 300 and from 2:03 PM to 2:35 PM the BFR was 350. There was no documentation why the BFR was not at the ordered rate of 400. An interview was conducted on 4/20/23 at 10:00 AM with EI # 1, Director of Operations, who confirmed there was no documentation why the BFR was not 400 as ordered. 5. PI # 1 was admitted to the facility on 3/4/23 with a diagnosis of ESRD. Review of the OSR revealed HD orders dated 3/4/23 which included BFR 400. Review of the TS dated 4/4/23 revealed the BFR was 350 from start of treatment 11:05 AM to 1:02 PM and the BFR was 300 from 1:02 PM to end of treatment 3:09 PM. There was no documentation why the BFR was not 400 as ordered. Review of the TS dated 4/15/23 revealed the BFR was 250 from start of treatment 11:11 AM to end of treatment 2:39 PM. There was no documentation why the BFR was not 400 as ordered. Review of the TS dated 4/18/23 revealed BFR was decreased to 300 at 12:33 PM until end of treatment 3:11 PM. There was no documentation why the BFR was not at the ordered rate of 400. An interview was conducted on 4/20/23 at 9:40 AM with EI # 1 who confirmed there was no documentation why the BFR was not 400 as ordered. 30952 6. PI # 3 was admitted to the facility on 11/29/19 with diagnoses including ESRD. Review of the OSR revealed HD orders dated 4/7/23 which included BFR 525 and DFR Autoflow 2.0 (800). Review of the TS dated 4/7/23 revealed the DFR was 600 from treatment start at 6:05 AM to 9:02. Further review of the 4/7/23 TS revealed the BFR was 300 from 6:46 AM until 9:02 AM. There was no reason documented why the DFR was 600 and not 800 as ordered and the BFR was 300 and not 525 as ordered. Review of the TS dated 4/12/23 revealed the BFR was 400 from 6:32 AM until 9:55 AM, treatment termination. There was no reason documented why the BFR was not 525 as ordered. An interview was conducted on 4/19/23 at 3:53 PM with EI # 1 who confirmed the staff failed to document the reason the BFR was not delivered as ordered and failed to administer the DFR per physician orders. 40119 7. PI # 7 was admitted to the facility on 2/14/22 with a diagnosis of ESRD. Review of the OSR revealed an order for PD dated 7/16/22 for CCPD (Continuous Cyclic Peritoneal Dialysis, which requires the use of a Cycler) seven days a week, five exchanges in which four would be with 2000 ml (milliliters) and the last exchange would be with 1000 ml. The average dwell time ordered at one hour and 40 minutes and the cyclic therapy time of eight hours and 30 minutes with an EDW of 71.5 kg. Review of the Treatment Summary PD revealed documentation of daily treatments from 2/19/23 to 4/2/23. Further review revealed documentation of 2000 (milliliters) under Dextrose 2.5 %. There was no documentation of the daily total number and amount of each exchange on the home treatment record. Review of the Home PD Nurse TS Monthly Check Off dated 3/15/23 and 4/3/23 revealed no documentation the patient was educated on documenting the daily total number and amount of each exchange on the home treatment record. In an interview conducted on 4/19/23 at 3:00 PM, EI # 10, Home PD Nurse, confirmed the 2000 ml amount was for one exchange and the daily total number and the amount of each exchange was not documented on the home treatment record. In an interview conducted on 4/20/23 at 8:45 AM, EI # 2, Director of Operations, Sister Facility, confirmed there was no documentation of the daily total number and amount of each exchange on the home treatment record from 2/19/23 to 4/2/23.