| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 152515 | A. BUILDING 00<br>B. WING | 05/01/2024 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP COD |
|---|---|
| FRESENIUS MEDICAL CARE FORT WAYNE JEFFERSON | 7836 W JEFFERSON BLVD STE LL10<br>FORT WAYNE, IN 46804 |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETION DATE |
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| V 0000<br><br>Bldg. 00 | | V 0000 | | |

This was a Post-Condition Revisit survey for the End Stage Renal Disease complaint survey conducted on 3/21/24. A full Federal CORE survey was conducted during the complaint survey due to condition-level findings.

During the initial survey, Complaint #IN00430123 was investigated with related and unrelated findings.

Survey Dates: 4/30/24, 5/01/24

Census by Service Type:
In-Center Hemodialysis: 52
Home Hemodialysis: 9
Home Peritoneal dialysis: 32

Total Active Census: 93

Isolation Room/Waiver: 1

During this Post Condition Revisit survey, two (2) condition-level deficiencies and ten (10) standard-level deficiencies were found corrected. No deficiencies were re-cited. One (1) new standard-level deficiency was cited.

QR 5/6/2024 by A2

| | | | | |
|---|---|---|---|---|
| V 0715<br><br>Bldg. 00 | 494.150(c)(2)(i)<br>MD RESP-ENSURE ALL ADHERE TO P&P<br>The medical director must- | | | |

| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE |
|---|---|---|
| Allison Cruea | Director of Operations | 05/17/2024 |

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determin other safegaurds provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclo days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| | (2) Ensure that-<br>(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers;<br><br>Based on observation, record review, and interview, the dialysis facility's medical director failed to ensure staff adhered to policies and procedures specific to patient assessment prior to discharge for 1 of 1 in-center hemodialysis (ICHD) patients observed to have change in condition (Patient #14).<br><br>Findings include:<br><br>The review of facility policy #45284 titled "Patient Assessment and Monitoring," dated 5/01/23, indicated the Registered Nurse (RN) was to re-assess "any findings addressed pre or during treatment" as needed and would notify the patient's physician of any abnormal findings in the patient's condition. Post-treatment assessment was to include the patient's "state of well-being ... general observations."<br><br>The review of facility policy #45265 titled "Nursing Supervision and Delegation," dated 11/06/23, indicated the RN was to review the patient's treatment record prior to discharge to "confirm [the] patient is stable for discharge."<br><br>During an ICHD treatment floor observation on 5/01/24 between 10:00 AM - 11:25 AM, the following was observed:<br><br>a. At 10:15 AM, Patient #14 was observed at Station 14 receiving dialysis treatment. Patient | V 0715 | On May 10, 2024, the Facility Administrator held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on Policies & Procedures). Please see the list of Policies and procedures or processes reviewed at the bottom of the plan. Emphasis will be placed on: The Registered Nurse will assess/re-assess any findings addressed pre or during treatment as needed. The Registered Nurse will assess/reassess any findings addressed pre or during treatment as needed. Prior to discharge, the RN must confirm the patient is stable for discharge and review the treatment record for: Slow/fast/irregular heart rate Low or high blood pressures Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight Heart rate <50 or >120 addressed by the registered nurse with documentation present. Blood pressures < 100 systolic or greater than 180 systolic addressed by the registered nurse with or documentation present. Reported fall, and if heparin was held and MD notified. Correct | 05/30/2024 |

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| | was leaning to left side; he/she appeared disoriented and lethargic. RN 1 was in the station attempting to reposition Patient<br><br>b. At 10:37 AM, Patient had his/her mouth hanging open with a disposable thermometer hanging out. Patient Care Technician (PCT) 4 entered the station to replace the thermometer and advise Patient to keep their mouth closed while his/her temperature was being obtained. Patient appeared disoriented and lethargic.<br><br>c. At 10:55 AM, 4 staff members were observed transferring Patient from the treatment chair to his/her wheelchair. Patient appeared weak.<br><br>d. At 11:00 AM, Patient was observed sitting in his/her wheelchair at a nurse's station while waiting on transportation. Patient mumbled he/she was "so cold." Patient had a jacket covering their shoulders; RN 2 assisted Patient with putting his/her arms through the jacket. Patient was leaning forward in the wheelchair and appeared disoriented and lethargic.<br><br>e. At 11:16 AM, Patient left the dialysis facility with transportation from his/her nursing facility.<br><br>The review of Patient #14's treatment flowsheet for 5/01/24 evidenced Patient's last treatment was 4/10/24. The flowsheet evidenced the following:<br><br>a. At 12:13 PM, RN 1 documented a late entry for events beginning at 5:30 AM. The nurse documented Physician 1 was called at 5:30 AM and a voicemail was left. At 7:40 AM, the facility had not yet received a call back from the physician. Nurse Practitioner (NP) 1 was contacted and "informed of [patient's] condition." The NP ordered for Patient to be sent to the | | dialysate prescription was delivered. Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations. Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. Observe the patient's overall condition during treatment. Report to the nurse any changes in patient's overall condition or any changes in mental status. All patients must be under visual observation by clinical staff during treatment. Report to the nurse any complaints by the patient during treatment. Document any findings and interventions in the medical record. Ensure vital signs and overall condition are stable for discharge. Evaluate access prior to discharge for: Bleeding Swelling Any changes during the treatment Ask the patient if he or she has anything more to report or any additional observations prior to discharge. The registered nurse will assess/re-assess post treatment as indicated. Document findings in the patient's record. Daily Treatment Record Review Prior to discharge, the RN must review the treatment record to: • Confirm patent is stable for discharge • Identify any process that could have resulted in the patient experiencing a safety event | |

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| | emergency department (ED). RN 1 documented Patient and his/her significant other refused to be sent to the ED. The nurse contacted Entity C, a skilled nursing facility where Patient resided, and informed facility of Patient condition. Entity C's nurse reported Patient was given Benadryl at 3 AM "and that's why [he/she was] so weak." The note indicated when Physician 1 returned the call, he advised to begin treatment and if Patient's condition worsened in 2 hours, Patient's treatment was to be terminated early and he/she was to be sent to the ED.<br><br>b. At 6:40 AM, RN 1 documented a nursing assessment, indicating Patient had been recently discharged from the hospital. The nurse documented Patient was "Alert, Oriented ... weak, wobbly sitting in chair, difficulty hold [his/her] head up."<br><br>c. At 6:53 AM, RN 1 documented 4 staff members were needed to transfer of Patient from his/her wheelchair to the treatment chair.<br><br>d. At 7:17 AM, RN 1 documented Patient "continues to try to get out of [his/her] chair. Turning body which is pulling on lines. [Patient] continually taking legs off leg/foot rest and hanging them off the side."<br><br>e. Patient was on dialysis treatment between 7:09 AM - 10:24 AM. Patient's blood pressure and heart rate were labile, with blood pressures ranging from 100/53 - 196/159 and heart rate ranging from 41 - 104. Patient's post-treatment vital signs included a blood pressure of 94/32, heart rate of 94, and temperature of 96.4 degrees Fahrenheit.<br><br>f. At 3:16 PM, RN 1 documented a late entry for | | or near miss The record must be reviewed for: • Slow/fast/irregular heart rate • Low or high blood pressures • Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight • Heart rate 100 addressed by the registered nurse with documentation present • Blood pressures < 100 systolic or greater than 180 systolic addressed by the registered nurse with or documentation present • Reported fall, and if heparin was held and MD notified. • Correct dialysate prescription was delivered External POC Report Page 2 of 2 *Change in level of consciousness, confusion, lethargy, seizure, gait pattern, speech pattern, weakness or numbness at any time * Document all findings in the patient's medical record. Effective May 11, 2024, the Facility Administrator or Charge Nurse will conduct daily audits utilizing Medical Record Audit Tool, on 5% of total treatments per day, for four weeks with a focus on ensuring the Registered Nurse assess the patient pre, during and post treatment for any abnormal findings. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAPI calendar. Monitoring will be done through the Medical Record | |

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| | 10:45 AM, indicating she performed a post-treatment evaluation at this time. The nurse documented Patient was alert, oriented, and there were no changes from Patient's pre-treatment assessment.<br><br>g. At 12:31 PM, RN 1 documented she reported to Entity C's nurse "how [Patient] did today and post [treatment vital signs]. No improvement in condition but no worse either." RN 1 documented the SNF nurse reported Patient was "very weak" prior to leaving the facility for dialysis treatment. The SNF nurse also reported Patient remained "weak ... not holding [his/her] head up" when he/she returned to Entity C from the dialysis facility.<br><br>h. At 12:33 PM, RN 1 documented she spoke with Physician 1, reporting Patient's vital signs "during and after [treatment] ... and no change in condition, either better or worse but the same. No orders received."<br><br>During an interview with Charge Nurse 4 on 5/01/24 beginning at 11:05 AM, the nurse reported Patient had been hospitalized for "several weeks" and 5/01/24 was the first day since hospitalization that Patient was receiving in-center hemodialysis. Charge Nurse 4 reported Patient's mental status had changed and he/she was now confused. When Patient arrived for his/her treatment earlier that day, he/she was "slumped over and disoriented," so facility staff had contacted NP 1. The nurse practitioner had recommended Patient be evaluated in the ED. Facility staff contacted Physician 1, who ordered for staff to initiate Patient's dialysis treatment as ordered. Charge Nurse 4 reported staff had not contacted Patient's nephrologist after Patient's treatment to report Patient's continued confusion and lethargy, as the | | Audit Tool. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Patient Assessment and Monitoring Nursing Supervision and Delegation Completion Date: 5/30/24 | |

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| | physician had advised to initiate Patient's treatment. Charge Nurse 4 reported the dialysis facility had received discharge paperwork regarding Patient's hospitalization, but the nurse had not yet had time to review the records. The nurse reported facility staff administered Vancomycin (an antibiotic) to Patient during his/her treatment for an unknown infection.<br><br>During an interview with RN 1 and Charge Nurse 4 on 5/01/24 beginning at 11:16 AM, RN 1 reported she spoke with a nurse at Facility C earlier that day regarding Patient's condition, and the facility nurse had reported Patient had received Benadryl (a medication used to treat allergic reactions, which has a side effect of drowsiness) at approximately 3 AM for insomnia. RN 1 reported Patient and his/her significant other were informed of NP 1's recommendation that Patient be evaluated in the ED, but both refused for Patient to be taken to the ED. Patient's significant other had informed RN 1 that Patient "came out like this" from the hospital. RN 1 reported she was planning on contacting Physician 1 to update him of Patient's condition but had not done so yet. RN 1 stated Physician 1 had advised to contact him if Patient's condition worsened during treatment. RN 1 reported Patient's condition had not worsened but had also not improved. Charge Nurse 4 reported there was nothing further the facility could do, since Patient and his/her significant other had refused for Patient to be taken to ED prior to the start of his/her dialysis treatment.<br><br>During an interview with Clinic Manager and Alternate Administrator on 5/01/24 beginning at 3:45 PM, Clinic Manager reported Patient had been hospitalized for approximately 2 weeks. Facility C had just admitted Patient on 4/30/24 and their staff did not know Patient's baseline mental | | | |

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| | status. Clinic Manager reported Patient's behavior during his/her 5/01/24 was a change from his/her dialysis treatments prior to hospitalization. Clinic Manager acknowledged Patient had a change in condition from his/her previous dialysis treatments, but reported since there was no change in Patient's mental status between the beginning and end of treatment, the facility was not required to notify the physician prior to Patient's discharge from the dialysis facility. | | | |