

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/11/2023
FORM APPROVED
OMB NO. 0938-039

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|---|--|---|--|--|--|--|----------------------------|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152500 | | X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING | | X3) DATE SURVEY COMPLETED 04/26/2023 | |
| NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE INDIANAPOLIS | | | | STREET ADDRESS, CITY, STATE, ZIP COD 2480 N MERIDIAN ST INDIANAPOLIS, IN 46208 | | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCY (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 |
| V 0000 Bldg. 00 | <p>This visit was for a Federal complaint investigation survey of an ESRD Supplier.</p> <p>Complaint#: IN 00406329- Unrelated federal deficiencies were cited.</p> <p>Survey Dates: 04-25-2023 and 04-26-2023</p> <p>Facility #: 005147</p> <p>CCN#: 152500</p> <p>Census by Service Type:</p> <p>In Center Hemodialysis Patients: 111 Home Hemodialysis: 4 Home peritoneal Dialysis: 21 Total Census: 136</p> <p>Stations: 41, including one isolation room. Isolation Room: 1</p> <p>QR by Area 3 on 4-28-2023</p> | | | V 0000 | <p><i>POC accepted on 5-11-23</i></p> <p><i>Deborah Franco, RN</i></p> | | |
| V 0143 Bldg. 00 | <p>494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and</p> <p>Based on observation, record review, and interview, the facility failed to ensure the staff</p> | | | V 0143 | <p><u>V 143 IC-Aseptic Techniques</u> <u>For IV Meds</u> On 04/27/2023, the Clinical</p> | | 05/10/2023 |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Betsey Farrar-McIntyre

Area Team Lead

05/08/2023

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards 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 disclosable 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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| | <p>initialed and dated opened medication and liquid nutrition in 3 of 4 observations.</p> <p>Findings Include:</p> <p>1. A review of a Fresenius Medical Care policy dated 02-06-2023, was provided by the Area Team Lead, Corp 2, on 04-26-2023 at 3:40 PM. The "Medication Preparation and Administration," indicated but was not limited to, " ... When preparing medications if the vial is not used immediately in its entirety, the nurse or PCT (Patient Care Technician) ... must place the date and time the vial was opened on the medication label along with their initials ... Expiration dates for all stored medications are to be monitored on a monthly basis ... Any multi-dose vials must be discarded 28 days after opening or per the manufacturer's expiration date ..."</p> <p>2. During a flash tour observation on 04-25-2023 at 9:15 AM, observed on the top of the medication station 4 open 32-ounce containers of LiquaCel liquid protein. The apple LiquaCel was dated open 10/22/2022, the lemon flavored LiquaCel was dated open 11-20-2022, and the grape, watermelon, and peach mango containers had no date opened or staff initials. The LiquaCel container's label for directions indicated to use the product within 3 months of opening.</p> <p>3. During an observation on 04-25-2023 at 10:45 AM, observed on the top of the medication area 4 an open 32-ounce containers of LiquaCel liquid protein. Observed in the second drawer in the black medicine cabinet under the medication area, 2 vials of Heparin 30,000 units/30-milliliter (mL) vials open without date open or staff initials, and an open vial of Doxercalciferol 4 micrograms (mcg)/mL. The apple LiquaCel was dated open</p> | | | | <p>Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure:</p> <ul style="list-style-type: none"> Medication Preparation and Administration <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> When preparing medications if the vial is not used immediately in its entirety, the nurse or PCT (if allowed by state regulations), must place the date and time the vial was opened on the medication label along with their initials. Note: To ensure all open vials are properly marked, the nurse must never walk away from an opened multi-dose vial without writing the date and time on the vial that was opened. Label any open multi-dose vial that is not used immediately and store vial accordingly. Expiration dates for all stored medications are to be monitored on a monthly basis. Expired medications are to be discarded via Fresenius Kidney Care off-site return program or in accordance with local and/or state law Any open multi dose vials must be discarded 28 days after opening or per manufacturer's expiration date. <p>Effective 04/27/2023, the Clinical Manager or designee will conduct weekly audits with a focus on ensuring all open medication/or</p> | | |

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| | <p>10/22/2022, the lemon flavored LiquaCel was dated open 11-20-2022, and the grape, watermelon, and peach mango containers had no date opened or staff initials. The LiquaCel container's label for directions indicated to use the product within 3 months of opening.</p> <p>4. During an observation on 04-26-2023 at 7:27 AM, observed on the counter of the medication area was a half-full vial of Heparin 30,000 units/30 mL vial open without a date open or staff initials.</p> <p>5. During an observation on 04-26-2023 at 4:15 PM, observed on the counter of the medication area was a half-full vial of Heparin 30,000 units/30 mL vial open without a date open or staff initials.</p> <p>During an interview on 04-25-2023 at 3:05 PM, the Director of Operations, Corp 1, and Area Team Lead, Corp 2, confirmed any open containers of medications and LiquaCel, the protein drink, are to be labeled date opened and staff initials.</p> | | | | <p>oral nutritional supplement are labeled with date/time and person initial's utilizing Medication Preparation and Administration Audit Tool for four weeks or until 100% compliance is achieved. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager 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 QAI 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 QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible</p> | | |

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| | | | for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. | | |