| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 152537 | A. BUILDING 00<br>B. WING | 05/18/2022 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP COD |
|---|---|
| FRESENIUS MEDICAL CARE CROWN POINT | 851 W BURRELL DR<br>CROWN POINT, IN 46307 |

| (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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| E 0000<br><br>Bldg. 00 | A Recertification (CORE) Survey was conducted by Healthcare Management Solutions, LLC on behalf of Centers for Medicare and Medicaid Services (CMS).<br><br>An unannounced on-site Recertification (CORE) survey (ASPEN #DNWR11) conducted at the above-named End Stage Renal Disease (ESRD) facility from 05/16/22 to 05/18/22 resulted in a finding of no deficiency respective to the Emergency Preparedness Program Condition for Coverage under 42 CFR 494.62.<br><br>Total Facility Census: 46<br><br>In-Center Hemodialysis: 46<br><br>Home Hemodialysis (HHD): 0<br><br>Peritoneal Dialysis (PD): 0<br><br>Nocturnal: 0<br><br>Pediatrics: 0<br><br>Sample Size: 8<br><br>Network 9 was contacted after entrance. | E 0000 | | |
| V 0000<br><br>Bldg. 00 | A Recertification (CORE) survey was conducted by Healthcare Management Solutions, LLC on behalf of Centers for Medicare and Medicaid Services (CMS). | V 0000 | | |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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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| | An unannounced on-site Recertification (CORE) survey (ASPEN #DNWR11) was conducted at the above-named End Stage Renal Disease (ESRD) facility from 05/16/22 to 05/18/22 resulted in a finding of substantial compliance respective to applicable Conditions for Coverage (CfC) under 42 CFR 494, Subpart A through D with the following standard-level deficiencies listed below.<br><br>Total Facility Census: 46<br><br>In-Center Hemodialysis: 46<br><br>Home Hemodialysis (HHD): 0<br><br>Peritoneal Dialysis (PD): 0<br><br>Nocturnal: 0<br><br>Pediatrics: 0<br><br>Sample Size: 8<br><br>Network 9 was contacted after entrance. | | | |
| V 0143<br><br>Bldg. 00 | 494.30(b)(2)<br>IC-ASEPTIC TECHNIQUES FOR IV MEDS<br>[The facility must-]<br>(2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and<br>Based on observation, interview, and policy review, the facility failed to ensure the staff followed policy to date, time, and initial open medication vials to ensure expired medications are not available for use. This deficient practice had the potential to affect the potency of the medication and could affect all 46 in-center | V 0143 | On 6/15/22, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:<br>· Medication Preparation and Administration version 8 | 07/02/2022 |

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| FRESENIUS MEDICAL CARE CROWN POINT | 851 W BURRELL DR<br>CROWN POINT, IN 46307 |

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| | hemodialysis patients receiving treatment at this facility.<br><br>Findings include:<br><br>Observation of the facility's medication preparation area on 05/17/22 at 8:15 AM showed the following undated, timed, and initialed medications: one open vial of Heparin (used to treat and prevent the blood clots) 30,000 units/30 (milliliter/unit of measure.)<br><br>During an interview on 05/17/22 at 8:30 AM, the Registered Nurse (RN)7, verified the staff are required to place the date and time on opened vials along with their initials.<br><br>A review of the facility's policy titled, "Medication Preparation and Administration," revised 05/02/22, indicated, "Labeling vials ...when preparing medications if the vial is not used immediately in its entirety, the nurse or Patient Care Technician (PCT (if allowed by state regulations) must place the date and time the vial was opened on the medication label along with their initials." | | Emphasis was placed on:<br>· 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.<br>· Label any open multi-dose vial that is not used immediately and store vial accordingly.<br>Effective 6/16/22, Clinic Manager or designee will conduct weekly audits with focus on ensuring staff follow policy to date, time, and initial open medication vials to ensure expired medications are not available for use utilizing Medication Preparation and Administration Audit for 4 weeks.<br>The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.<br>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.<br>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.<br>The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the | |

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| | | | resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.<br>The QAI 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.<br>The Plan of correction is reviewed in QAI monthly.<br>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.<br>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.<br>Completion 7/2/22. | |
| V 0504<br><br>Bldg. 00 | 494.80(a)(2)<br>PA-ASSESS B/P, FLUID MANAGEMENT NEEDS<br>The patient's comprehensive assessment must include, but is not limited to, the following:<br><br>Blood pressure, and fluid management needs.<br>Based on record review, interview, and policy review, the facility staff failed to monitor and document patient treatments as required for two of five in-center patient (Patients (P)3, and P4) treatment records reviewed. Failure to monitor and document treatment findings could negatively | V 0504 | On 6/15/22, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:<br>·Patient Assessment and | 07/02/2022 |

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| | impact the effectiveness of the dialysis treatment for the 46 in-center hemodialysis patients receiving dialysis treatments at this facility.<br><br>Findings include:<br><br>1. Review of P3's medical record revealed a history of diabetes. The six "Treatment Sheet" records, dated from 05/02/22 and 05/13/22, revealed two of six "Treatment Sheets" failed to document the monitoring and assessment of the patient's blood pressure.<br><br>05/02/22 - no documentation was recorded between 10:02 AM and 11:04 AM (62 minutes) to verify monitoring and assessment of P1's blood pressure.<br><br>05/11/22 - no documentation was recorded between 12:33 PM and 1:35 PM (62 minutes) to verify monitoring and assessment of P3's blood pressure.<br><br>2. Review of P4's medical record revealed a history of high blood pressure. The six "Treatment Sheet" records, dated from 05/04/22 and 05/16/22, revealed two of six Treatment Sheets failed to document the monitoring and assessment of the patient's blood pressure (bp).<br><br>05/09/22 - no documentation was recorded between 6:01 AM and 7:04 AM (63 minutes) to verify monitoring and assessment of P2's blood pressure.<br><br>05/11/22 - no documentation was recorded between 7:04 AM and 8:02 AM (58 minutes) to verify monitoring and assessment of P2's blood pressure. | | Monitoring version 3<br>Emphasis was placed on:<br>·Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations.<br>Effective 6/20/22, Clinic Manager or designee will conduct weekly treatment sheet audits on 10% of completed treatments with focus on ensuring vital sign monitoring and safety checks are completed every 30 minutes utilizing Medical Record Documentation (ICHD) Audit for 4 weeks or until 90% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.<br>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.<br>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.<br>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 | |

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| | Review of the facility's policy titled, "Patient Monitoring and Safety Checks During Hemodialysis Treatment," revised 11/01/2021, indicated, "Monitoring During Treatment-Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations in the FKC (Fresenius Kidney Care) Treatment Record." | | of all identified issues.<br>The QAI 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.<br>The Plan of correction is reviewed in QAI monthly.<br>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.<br>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.<br>Completion 7/2/22. | |