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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>152585 | X2) MULTIPLE CONSTRUCTION<br>A. BUILDING 00<br>B. WING _____ | X3) DATE SURVEY COMPLETED<br><br>06/10/2015 |
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| NAME OF PROVIDER OR SUPPLIER<br><br>FRESENIUS MEDICAL CARE SHADELAND STATION | STREET ADDRESS, CITY, STATE, ZIP CODE<br>7155 SHADELAND STATION STE 130<br>INDIANAPOLIS, IN 46256 |
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| V 0000<br><br>Bldg. 00 | <p>This was a revisit for the recertification survey conducted on 4-27-15, 4-29-15, 4-30-15, and 5-1-15.</p> <p>Survey Date: 6-10-15</p> <p>Facility #: 003483</p> <p>Medicaid Vendor #: 200424460</p> <p>One (1) condition and 11 standards were found to be corrected. Two (2) standard deficiencies remain not corrected and were re-cited and 1 new standard deficiency was cited.</p> <p>QR: JE 6/15/15</p>   | V 0000        |  |                      |
| V 0143<br><br>Bldg. 00 | <p>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 review of facility policy, the facility failed to ensure intravenous medications had been prepared in accordance with facility policy in 1 (# 1) of 1 parenteral</p> | V 0143        | The Governing Body for the facility met on 6/25/15 to review the Statement of deficiencies and developed the plan of Correction. The Director of Operations reviewed the following policies ""Medication Preparation and | 07/01/2015           |

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

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days 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 14 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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|                    | <p>medication preparation and administration observations completed.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>1. Employee Y, a registered nurse (RN), was observed to prepare the intravenous medication, Hectorol, for administration to patient number 18 on 6-10-15 at 10:15 AM. The RN was observed to remove the protective caps from 2 Hectorol vials. The RN failed to wipe the rubber stoppers with alcohol prep pads prior to drawing up the medication into the syringe.</li> <li>2. The Director of Operations, employee CC, indicated, on 6-10-15 at 12:00 PM, the RN had not followed facility policy by failing to wipe the rubber stopped with an alcohol prep pad prior to drawing up the medication.</li> <li>3. The facility's 1-28-15 "Medication Preparation and Administration" procedure number FMS-CS-IC-I-120-040C states, "Remove protective cap from vial and wipe rubber stopper with alcohol prep pad."</li> </ol> |               | <p>Administration" policy number FMS-CS-IC-I-120-040C with the Clinical Manager on 6/10/15 emphasizing his responsibility to ensure all staff members are educated on the policies, competency is assessed and staff understands the requirement to follow policies and procedures as written. All staff were In serviced on 6/12/15 per the Charge RN and CM on this policy to ensure all staff removed protective cap from medication vials and wiped rubber stopper with alcohol prep pad.</p> <p>The Clinical Manager or designee will ensure that infection control/Medication prep and Administration audits utilizing the QAI Infection Control audit tool are done daily for 4 weeks, monthly for 3 months, and then as determined by the QAI calendar. Any deficiencies noted during the audits will be referred immediately to the Clinical Manager will utilize option of formal corrective action that should/could be taken for specific staff, who for whatever reason, continue to practice outside of policy.</p> <p>The Clinical Manager is responsible to evaluate and present the audit findings in the monthly QAI meeting/minutes. The QAI Committee is responsible to review analyze and trend all monitoring results to</p> |                      |

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| V 0407<br>Bldg. 00 | <p>494.60(c)(4)<br/>PE-HD PTS IN VIEW DURING TREATMENTS<br/>Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).<br/>Based on clinical record and facility policy review and interview, the facility failed to ensure vital signs and machine checks had been completed at least every 30 minutes in accordance with facility policy in 2 (#s 3 &amp; 4) of 5 records reviewed.</p> <p>The findings include:</p> <p>1. The facility's 8-20-14 "Patient Monitoring During Patient Treatment" policy number FMS-CS-IC-I-110-133A states, "Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently, as needed . . . . Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible . . . . Check machine settings and measurements and document at the initiation of dialysis and at every safety check."</p> <p>2. Clinical record number 3 failed to evidence vital signs and safety checks</p> | V 0407        | <p>ensure resolution is both occurring and is sustained.</p> <p>The Director of Operations (DO) met with the Clinical Manager (CM) on 6/10/15 and reviewed FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment Policy", emphasizing his responsibility to ensure all staff members are educated on the policies, competency is assessed and staffs are required to follow policy and procedure as written.</p> <p>Staff were reeducated by the CM and CN 6/12/15 on the policy listed above, with an emphasis placed on the following responsibilities:</p> <ul style="list-style-type: none"> <li>Vital signs will be monitored at initiation of treatment of dialysis and every 30 minutes, or more frequently as necessary.</li> <li>Appropriate interventions in response to changes in vital signs, treatment parameters, or machine adjustments shall be documented in the treatment record including referral to the RN and assessment findings.</li> </ul> <p>To ensure full compliance, the</p> | 07/01/2015           |

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| V 0543<br><br>Bldg. 00   | <p>had been completed at least every 30 minutes.</p> <p>A hemodialysis treatment flow sheet dated 6-5-15 evidenced the patient had been checked at 1:40 PM and not again until 2:43 PM, a period of 1 hour and 3 minutes between checks.</p> <p>3. Clinical record number 4 failed to evidence vital signs and safety checks had been completed at least every 30 minutes.</p> <p>A hemodialysis treatment flow sheet dated 6-8-15 evidenced the patient had been checked at 7:38 PM and not again until 8:54 PM, a period of 1 hour and 16 minutes between checks.</p> <p>4. The Director of Operations, employee CC, indicated, on 6-10-15 at 12:00 PM, the vital signs and safety checks had not been completed at least every 30 minutes in records 3 and 4.</p> <p>494.90(a)(1)<br/>POC-MANAGE VOLUME STATUS<br/>The plan of care must address, but not be limited to, the following:</p> |   | <p>Clinical Manager or charge nurse will immediately begin daily observation audits on the treatment floor; this audit will specifically include real time review of the ChairSide flowsheets for compliance with the bullet points noted above. Any deficiency identified will immediately be corrected. The Clinical Manger will be notified of the audit findings. The Clinical Manager will be responsible to address and counsel staff identified in the deficiency, this counsel may include formal corrective action. The Clinical Manager or designee will audit 100% of treatment sheets before close of the business day to ensure compliance. These audits will continue until full compliance is achieved; at that point the audits will revert back to the CQI calendar.</p> <p>The Clinical Manager is responsible to evaluate and present the treatment sheet audit findings in the monthly QAI meeting/minutes. The QAI Committee will perform a root cause analysis and document in the QAI minutes to ensure resolution is both occurring and is sustained.</p> |                      |   |

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|                    | <p>(1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status;</p> <p>Based on clinical record review and interview, the facility failed to ensure medications for elevated blood pressure readings had been administered as ordered in 2 (#s 9 and 17) of 3 records reviewed of patients with medication orders for elevated blood pressure readings.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>Clinical record number 9 included physician orders dated 5-27-15 that stated, "Clonidine HCl [hydrochloride] 0.1 mg [milligram] oral during dialysis prn [as needed]-may repeat x1 [times one] Monitor x 1 hour then given if SBP [systolic blood pressure] &gt; 180 or DBP [diastolic blood pressure] &gt; 100."</li> <li>Clinical record number 17 included physician orders dated 5-27-15 that stated, "Clonidine HCl 0.1 mg oral prn</li> </ol> <p>A hemodialysis treatment flow sheet dated 6-5-15 evidenced a blood pressure reading of 189/61 at 5:17 PM, 196/64 at 5:34 PM, 203/65 at 6:02 PM, and 189/66 at 7:02 PM. The flow sheet failed to evidence any Clonidine had been administered per the physician's order.</p> | V 0543        | <p>The Director of Operations reviewed the following policies FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care Policy" and FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment" with the Clinical Manager and Charge RN on 6/10/15 emphasizing their responsibility to ensure all staff members are re-educated on the policies, competency is assessed and staff understands the requirement to follow policies and procedures as written.</p> <p>A mandatory in-service was conducted on 6/12/15 and the CM/CN reviewed &amp; re-educated staff on the following policies:</p> <ul style="list-style-type: none"> <li>FMS-CS-IC-I-110-133A "Monitoring During Patient Treatment"</li> <li>FMS-CS-IC-I-110-125A "Comprehensive Interdisciplinary Assessment and Plan of Care Policy"</li> </ul> <p>Special emphasis was placed on ensuring that the patient's EDW is addressed each treatment; prescribed dose of dialysis is sustained; hypertensive monitoring and interventions are delivered according to the physician's prescription and requirement to achieve adequate</p> | 07/01/2015           |

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|                    | <p>-may repeat X 1 Monitor x1 hour. Give for syst [systolic] &gt; 180 dias [diastolic] &gt; 100."</p> <p>A. A hemodialysis treatment flow sheet dated 6-3-15 evidenced a blood pressure reading of 198/68 at 7:01 AM and 186/67 at 7:03 AM. The flow sheet failed to evidence any Clonidine had been administered as ordered. The flow sheet evidenced the Acetaminophen 325 mg had been administered at 7:15 AM for complaints of "headache."</p> <p>B. A hemodialysis treatment flow sheet dated 6-5-15 evidenced blood pressure readings of 181/64 at 6:47 AM, 184/60 at 7:06 AM, 213/65 at 7:33 AM, 210/60 at 8:06 AM, 195/64 at 8:33 AM, 200/60 at 9:06 AM, 213/60 at 9:35 AM, 185/60 at 10:05 AM, and 196/62 at 10:22 AM. The flow sheet evidenced the registered nurse (RN), employee I, had not administered the Clonidine 0.1 mg until 8:41 AM and had not repeated the dose per the physician's order.</p> <p>3. The Director of Operations, employee CC, indicated, on 6-10-15 at 12:00 PM, the Clonidine had not been administered as ordered in record number 17.</p> |               | <p>clearance.</p> <p>This will be monitored by the nurse using the rounding tool.</p> <p>Additionally, the Clinical Manager/Charge RN reviewed and re-educated all staff on proper administration of Clonidine, per physician order, for any blood pressure outside of parameters ordered per MD on 6/12/15. The Clinical Manager will also meet with the interdisciplinary team to ensure any target weight issues and blood pressure issues are addressed on the POC. The Clinical Manager or designee will review 100% of patient charts, flow sheets, and POC's each month to ensure Clonidine is given per physician order as well as all target weight and blood pressure issues are addressed on the patient's plan of care until compliance is achieved. The Clinical Manager or charge nurse will immediately begin daily observation audits on the treatment floor; this audit will specifically include real time review of the ChairSide flowsheets for compliance with the bullet points noted above. Any deficiency identified will immediately be corrected. The Clinical Manger will be notified of the audit findings. The Clinical Manager will be responsible to address and counsel staff identified in the deficiency, this</p> |                      |

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|  |  |   | <p>counsel may include formal corrective action.</p> <p>These audits will continue until full compliance is achieved; at that point the audits will revert back to the CQI calendar.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly in QAI. The QAI Committee will perform a root cause analysis and document in the QAI minutes.</p> |                      |   |