

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

PRINTED: 04/16/2025
FORM APPROVED
OMB NO. 0938-0391

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 433513 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 04/03/2025 |
| NAME OF PROVIDER OR SUPPLIER MONUMENT HEALTH DIALYSIS LLC | | | STREET ADDRESS, CITY, STATE, ZIP CODE 955 EAST NORTH STREET STE 200 RAPID CITY, SD 57701 | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (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 000 | INITIAL COMMENTS A recertification health survey for compliance with 42 CFR Part 405, Subpart U, requirements for End Stage Renal Disease Services, was conducted from 4/1/25 through 4/3/25. Monument Health Dialysis, LLC was found not in compliance with the following requirements: V117, V142, V229, V562, and V715. | V 000 | | | |
| V 117 | IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS CFR(s): 494.30(a)(1)(i) Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients. This STANDARD is not met as evidenced by: Based on observation, interview, and policy review, the provider failed to ensure: *One of one heparin (blood thinner medication) | V 117 | 1)The facility will meet the V117 standard by updating Heparin Policy 512 to include staff guidance on 1. Proper areas for clean preparation and handling of medication 2. Proper storage of medication 3. Defining CLEAN areas for medication preparation and administration 4. Timing of acceptable medication preparation and length of medication stability once drawn in secondary syringe. 5. Returning medication to clean secured area when not in use 6. Not carrying medication from station to station. The Policy changes have been made by the AOD in consultation with corporate RNs, discussed with Medical Director, and will be formally approved at the 4/22/25 Governing Body Meeting on 4/22/2025. 2)The facility will provide and document staff education to ensure Policy # 512 Heparin Administration will be followed. This will be accomplished by the Nurse Manager. This training will be accomplished by 05/05/2025. 3) The facility will validate staff training by the DCI Nurse Manager assuring completion of Skills Checklist all clinical staff have job responsibilities that include Heparin administration. 4)The facility will include the DCI Heparin Administration Skills Checklist is part of new employee packets to be reviewed and validated during orientation of new clinical employees 5)The facility will ensure ongoing compliance with standard V117 by performing Audits 2 X weekly for 4 consecutive weeks, then 1X weekly for 4 weeks, then quarterly through 2025 and periodically thereafter. Audits will be presented for review at the monthly QAPI meeting and the continued frequency will be determined based on process adherence and be overseen by the Nurse Manager and AOD. | begun 04/06 and completed by 05/18/2025 | |

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

TITLE

(X6) DATE

Kristin Chillemi

RN, Area Operations Director

04/23/2025

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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| V 117 | <p>Continued From page 1</p> <p>vial had not been transported in the pocket of a lab coat and kept secure.</p> <p>*Medications were prepared in a clean dedicated area by one of one registered nurse (RN) K.</p> <p>Findings include:</p> <p>1. Observation on 4/1/25 at 2:30 p.m. revealed a staff lab coat hanging near an exit door with a heparin vial inside one of the pockets.</p> <p>2. Observation and interview on 4/2/25 at 8:15 a.m. with RN K revealed:</p> <p>*An unoccupied computer screen and keyboard sitting on top of a desk with:</p> <ul style="list-style-type: none"> -Multiple unopened 10 ml (milliliters) syringes. -Multiple unopened medic anti-stick needle connectors (devices to reduce the risk of accidental needlesticks). -One opened bottle of personal lotion. -A stethoscope. -One unopened package of gauze dressing. -Multiple handwriting pens. <p>*She confirmed she had prepared heparin medication for patients at that computer station.</p> <p>*She agreed preparing medications at a computer station would not have been considered a clean, designated area for that task.</p> <p>*She confirmed there were designated areas located in each pod to draw up medications.</p> <p>Interview on 4/2/25 at 10:45 a.m. with director of dialysis B revealed:</p> <p>*She had not been aware that some of the staff had not been preparing their Heparin for patient administration at the designated clean areas for each pod.</p> <p>*She stated:</p> <p>- "Each pod has a designated clean area for them</p> | V 117 | | | |

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| V 117 | <p>Continued From page 2 to prepare it [Heparin]. -The computer and desk area is not a designated spot because it's not clean." *She would have expected the staff to prepare the Heparin for patient administration in the designated clean areas at each of the eight pods.</p> <p>3. Interview on 4/3/25 at 10:10 a.m. with director of dialysis B revealed: *It was not appropriate for staff to carry vials of heparin in their lab coats. *Heparin should have been stored in a secured location until the time of use then prepared for patient use at the designated clean area.</p> <p>4. Review of the provider's undated Medication Administration Skills Checklist revealed: *"Medication is prepared in a clean dedicated area; Discards med [medication] if placed on a contaminated surface. *Returns medications to locked cabinet/refrigerator when not using. *Medication is not left at [the] station or [an] unsecure area."</p> <p>Review of the provider's January 2025 Use of Multiple dose Vials policy revealed: *"Clean areas should be clear designated for the preparation, handling and storage of medications. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. *Do not store or transport vials in clothing or pockets."</p> <p>Review of the provider's undated Administration and Use of Intravenous Heparin policy revealed, "When multiple dose medication vials are used (including vials containing diluents), prepare</p> | V 117 | | | |

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| V 117 | Continued From page 3 individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient." Review of the provider's November 2021 education on Heparin and Labs revealed: *"Remember to always draw up medication in a clean area away from dialysis stations. *Do not carry medications from station to station. *Do not carry medication vials, syringes, alcohol swabs, or supplies in pockets. *Be sure to prepare the medication in a clean area away from the patient station and bring it to the patient station for that patient only at the time of use." | V 117 | | | |
| V 142 | IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P CFR(s): 494.30(b)(1) The facility must- (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; This STANDARD is not met as evidenced by: Based on observation and interview, the provider failed to ensure fifteen randomly identified medications in one of one cabinet had not been kept available for patient use beyond the manufacturers' expiration dates. Findings include: 1. Observation on 4/1/25 at 10:15 a.m. of a large unlocked metal cabinet located between all four dialysis pods revealed: *Inside the cabinet were multiple medications | V 142 | The facility will ensure compliance with Standard V142 by 1)Removing the expired medication found during the SD DOH survey on 4/1/25 already accomplished by the Nurse Manager. 2)Performing weekly and monthly process changes per Policy 700 DCI Corporate policy Medication discussed with Medical Director and adopted by the Governing Body on 4/22/2025. This will include weekly documentation by the Charge RN doing daily medication count, of the expiration dates and removal if found expired. This is accomplished by the AOD 3)Nurse Manager will document education to RNs functioning in the Charge RN role regarding added responsibility of documenting expiration dates by 05/05/2025. 4)Month End Inventory count sheet will contain the expiration dates of each medication and will be kept on file for verification. At month end the Nurse Manager or AOD will perform medication inventory and this will serve as the audit process of the weekly Charge RN expiration verification. The audit will be presented for review at the monthly QAPI meeting and continuation or extension of the audit process will be based on process compliance. | | 05/18/2025 |

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| V 142 | <p>Continued From page 4</p> <p>available to the patients during their dialysis treatments.</p> <p>*The following medications had expired per the manufacturers' recommended for use date:</p> <p>-Thirteen 1.3 milliliter vials of Korsuva (used for moderate to severe itching associated with patients undergoing hemodialysis) had an expiration date of March 2025.</p> <p>-Two 2 gram vials of Ceftazidime (antibiotic used to treat bacterial infections) had an expiration date of March 2025.</p> <p>Interview on 4/1/25 at 10:30 a.m. with charge nurse A regarding the above observation revealed:</p> <p>*The cabinet was used to store medications that were used for the dialysis patients.</p> <p>*She was the charge nurse that day and had unlocked it when she came in for work that morning.</p> <p>-She would have locked the cabinet back up at the end of the day to secure the medications.</p> <p>*She was not aware of the expired medications that were in the cabinet.</p> <p>*She agreed that those medications had expired and should not have been in the cabinet and kept for patient use.</p> <p>*She stated:</p> <p>- "The charge nurse is responsible to count and check the expiration dates on the meds every day."</p> <p>- "I must have missed those with my count today."</p> <p>- "We don't use the Korsuva anymore and was [were] waiting for it to expire."</p> <p>Interview on 4/1/25 at 2:20 p.m. with director of dialysis B revealed:</p> <p>*She was not aware there were expired medications located in the cabinet by the dialysis</p> | V 142 | | | |

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| V 142 | Continued From page 5 pods. *She stated: -"The charge nurses are supposed to count those meds every day and check for expiration dates at the same time." -"And then there is also a monthly count of the meds when the dates are checked again." *They did not have a policy or formal process for checking medications for expiration dates to ensure they had not been available for use. | V 142 | | | |
| V 229 | MIXING SYSTEMS-PERM RECORD/VERIF TEST CFR(s): 494.40(a) 5.4.4.1 Mixing systems: perm record/verification testing In addition to container labeling, there should be permanent records of batches produced. These records should include the concentrate formula produced, the volume of the batch, the lot numbers of powdered concentrate packages, the manufacturer of the powdered concentrate, the date and time of mixing, any test results, the person performing the mixing, the person verifying mixing and test results, and the expiration date (if applicable). 6.4.1 Mixing systems Acid and bicarbonate concentrates may be tested by using conductivity or by using a hydrometer. Concentrates should not be used or transferred to holding tanks or distribution systems until all tests are completed. The test results and verification that they meet all applicable criteria should be recorded and signed by the individuals performing the tests. This STANDARD is not met as evidenced by: | V 229 | The facility will ensure compliance with Standard V229 by 1)Documentation of re-education on Acid and Concentrate Mixing Policy # 409.1 Acid Mixing will be accomplished by AOD on 04/23/2025. 2)Audit acid record logs 1 X weekly for 8 weeks and quarterly through 2025 for compliance with specific gravity verification. Periodic audits thereafter performed by Nurse Manager or AOD and after initial audit period(above)performed by the technical team. 3)AOD and Lead Technician will present and review audit results with Medical Director in monthly QAPI meetings and continuation or extension of audits will be based on process compliance. | 05/18/2025 | |

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| V 229 | Continued From page 6 Based on acid concentrate log review, interview, and policy review, the provider failed to ensure acid concentrate specific gravity test results had been properly documented for two of two acid batch mixers of 2 potassium (K) dialysate concentration and 3K dialysate concentration. Findings include: 1. Review of the provider's 2K dialysate concentration and 3K dialysate concentration specific gravity ranges for dry acid product logs from 11/1/24 through 4/2/24 revealed: *Specific gravity test results for 2K dialysate concentration had not been documented on: -11/10/24. -11/15/24. -12/4/24. *Specific gravity test results for 3K dialysate concentration had not been documented on 12/30/24. Interview on 4/2/25 at 10:26 a.m. with lead technician L revealed she confirmed the above listed test results had not been documented but they should have been. Review of the provider's undated Acid Concentrate Mixing, Transferring, and Rinsing of the Rockwell Mixer policy revealed test results of the specific gravity check should have been documented on the acid concentrate batch mix log after each test. | V 229 | | | |
| V 562 | POC-PT/FAMILY EDUCATION & TRAINING CFR(s): 494.90(d) The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the | V 562 | | | |

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| V 562 | <p>Continued From page 7</p> <p>dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, document review, record review, and policy review, the provider failed to develop an effective process on patient education related to emergency disconnection to ensure patient safety for three of eight sampled patients (1, 3, and 10).</p> <p>Findings include:</p> <p>1. Interview on 4/1/25 at 9:30 a.m. with patient 10 revealed: *She had started hemodialysis treatments on 3/25/25. *Her treatment schedule had been three days a week and that day (4/1/25) was her fourth treatment. *She had a central venous catheter (CVC) that was temporarily placed for dialyzing until a surgeon was available to surgically place a fistula (surgically created connection between an artery and vein for hemodialysis treatments). *She confirmed she had not received education related to emergency disconnection from a dialysis machine. *She stated: -"No, no one has said anything about me knowing how to disconnect myself from that [dialysis machine]." -"Do you suppose I should ask? That is kind of important I guess."</p> <p>2. Interview on 4/1/25 at 11:00 a.m. with patient 1</p> | V 562 | <p>The facility will ensure compliance with Standard V562 by:</p> <p>1)An audit of all patients admitted since Joint Venture November 1, 2024 will be performed to assure all patients have current EP training documented in the Red EP binders for Hemodialysis patients. This will be accomplished by the Nurse Manger utilizing the front office staff.</p> <p>2) Identified patients will receive EP training by the Nurse Manger designee by 05/05/2025.</p> <p>3)The Transitional Care Coordinator will add the EP four square documentation to the patient admission training materials to be accomplished on all new admissions going forward.</p> <p>4)Monthly, prior to QAPI meeting, the Nurse Manager designee will generate the report of newly admitted Hemo patients. The designee will then review the Red EP binders to confirm emergency preparedness training has occurred on all recently admitted patients.</p> | 05/18/2025 | |

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| V 562 | <p>Continued From page 8</p> <p>revealed:</p> <ul style="list-style-type: none"> *He had started hemodialysis treatments about five weeks ago on 2/29/25. *He had a CVC placed on 2/19/25 that was temporarily placed for dialyzing until his fistula was approved for use. *He had not received education related to emergency disconnection from a dialysis machine. *He stated: <ul style="list-style-type: none"> - "No, No one has talked to me about disconnecting from this machine in an emergency." - "That's probably important and I should know that." - "They discussed a lot of things when I started so maybe I just don't remember." <p>3. Observation and review on 4/1/25 of a red binder located at the nurse's station in pod 3 revealed:</p> <ul style="list-style-type: none"> *The binder was labeled Emergency Preparedness/Education/Disconnect/Cut & Go. *The binder contained all the patients who received treatments in pods 3 and 4. *Each patient had a form that the staff were to document on every quarter supporting the patients had received emergency education on the following topics: <ul style="list-style-type: none"> - Clamp fistula/bloodline. - Disconnect lone. - Evacuation Routes. - Hand crank. - When to call for help. - Emergencies: non-clinic hours. - Review of patient rights and responsibilities. *The education included documentation to support the patient's understanding of the education and completing a return demonstration. | V 562 | | | |

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| V 562 | <p>Continued From page 9</p> <p>*The staff and patients were to have signed and dated the form to support the education had occurred.</p> <p>*Patient 1 had a form assigned to him for the emergency education.</p> <p>-There was no documentation on the form to support emergency education had been provided to him.</p> <p>*Patient 10 did not have a form to support the staff had provided her with initial emergency education on how to disconnect from the machine in an emergency.</p> <p>4. Observation and interview on 4/1/25 at 3:30 p.m. with registered nurse (RN) K regarding the above emergency preparedness binder revealed:</p> <p>*She confirmed the forms were used to educate the patients on how to disconnect from the dialysis machine in an emergency.</p> <p>*Each patient should have received that education once per quarter.</p> <p>*She confirmed that:</p> <p>-Patient 1 had been receiving treatments for about five weeks and should have received the emergency education.</p> <p>-She was not sure why there was no documentation to support that education had occurred.</p> <p>*She stated:</p> <p>-"Someone just has to complete the education within the quarter."</p> <p>-"It can be done by anyone, a tech or a nurse."</p> <p>-"No one is assigned it we are just told when we need to do it."</p> <p>-"[Patient 10] wouldn't have a sheet, she's too new."</p> <p>*She was not sure when patient 10 should have been provided with the emergency disconnect education.</p> | V 562 | | | |

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| V 562 | <p>Continued From page 10</p> <p>*She stated: -"She's just too new." -"They tell us when to do it so I'm assuming it's still too soon for her." -"We'd do it for her I guess."</p> <p>5. Interview on 4/1/25 at 11:03 a.m. with patient 3 revealed: *He had started dialysis with the provider in November 2024. *He had a dialysis catheter placed on 3/3/25 due to his fistula not working correctly. *He had not received education related to emergency disconnection from a dialysis machine. *He stated: -"I have thought if there was an emergency, how would I disconnect myself from this machine." -"I better ask the staff on what to do."</p> <p>6. Observation and interview on 4/1/25 at 11:20 a.m. with charge nurse A regarding education related to emergency procedures revealed: *All patients should have received education related to emergency procedures including emergency disconnection upon initiation of dialysis and quarterly thereafter. *Documentation of that education was kept in a binder located at the nurse's station. *The education provided to patients included: -Clamp fistula/bloodline. -Disconnect lone. -Evacuation Routes. -Hand crank. -When to call for help. -Emergencies: non-clinic hours. -Review rights/responsibilities. *The education included an evaluation for staff to document the patient's understanding and return</p> | V 562 | | | |

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| V 562 | <p>Continued From page 11</p> <p>demonstration of the education provided.</p> <p>-Staff were to sign, date and include, the patient's signature on that form.</p> <p>*The emergency procedures education form located in pod 2's binder for patient 3 was blank.</p> <p>*She confirmed patient 3 did not have any documentation recorded related to the emergency procedures education.</p> <p>*She stated the patient had been in the hospital recently so he had missed the quarterly education but should have had the education when he began dialysis in November 2024.</p> <p>Review of patient 3's medical record revealed no documented education related to emergency procedures had been provided to him.</p> <p>7. Observation and interview on 4/1/25 at 3:45 p.m. with director of dialysis B revealed:</p> <p>*She confirmed there was no emergency procedures document in the binder for patient 10.</p> <p>*She stated:</p> <p>- "She's too new with dialysis and would not have it completed yet."</p> <p>- "So, no I would not expect to see a sheet in here on her."</p> <p>- "When they are new the patients are typically educated on it within the month."</p> <p>*She further confirmed that patient 1 had a form in the binder for emergency procedure education.</p> <p>*She stated:</p> <p>- "He's been here 5 weeks so yes, he should have had the education."</p> <p>- "The sheets in here so it should be done."</p> <p>- "The patients get education every quarter and within a month of starting [dialysis treatments]."</p> <p>- "We don't have a policy for this, the staff just follow the directions on the sheet in front here."</p> | V 562 | | | |

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| V 562 | Continued From page 12 8. Review of the providers Emergency Off Review document located in front of the binder had no documentation or process to support: *How soon a patient should have received emergency procedures education after their admission to dialysis. *How often patients should have had a refresher course on emergency procedures after the initial education was provided. *Who had been responsible for ensuring the education had been completed. | V 562 | | | |
| V 715 | MD RESP-ENSURE ALL ADHERE TO P&P CFR(s): 494.150(c)(2)(i) The medical director must- (2) Ensure that- (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; This STANDARD is not met as evidenced by: Based on observation, interview, and policy review, the provider failed to ensure: *Six of ten heparin (blood thinner medication) syringes had been labeled with the time and staff initials of those who prepared it. *Seven of 12 heparin syringes had not been prepped prior to the patients' arrival. *Three of three heparin syringes would have been administered by the staff who prepared the heparin for patient administration. *Two of two heparin vials and three of three heparin syringes had been placed in a secure area or not left unsecured at the nurse's station. *An expiration time was documented for 12 of 12 | V 715 | 1)The facility will meet the V715 standard by updating Heparin Policy 512 to include staff guidance on 1. Proper areas for clean preparation and handling of medication 2. Proper storage of medication 3. Defining CLEAN areas for medication administration 4. Timing of acceptable medication preparation and length of medication stability once drawn in secondary syringe 5.Returning medication to clean secured area when not in use 6. Not carrying medication from station to station. The Policy changes have been made by the AOD, discussed with Medical Director, and will be formally approved at the 4/22/25 Governing Body Meeting on 4/22/2025. 2)The facility will provide and document staff education to ensure Policy 512 Heparin Administration will be followed. This will also be accomplished by the Nurse Manager and AOD. by 05/05/2025. 3) The facility will validate staff training by the DCI Nurse Manager assuring completion of Skills Checklist all clinical staff have job responsibilities that include Heparin administration by 05/05/2025. 4) The facility will include the DCI Heparin Administration Skills Checklist is part of new employee packets to be reviewed and validated during orientation of new clinical employees effective 04/21/2025. 5)The facility will ensure ongoing compliance with standard V117 by performing Audits 2 X weekly for 4 consecutive weeks, then 1X weekly for 4 weeks, then quarterly through 2025 and periodically thereafter. This will be accomplished by the Nurse Manager and AOD or their designee. | 05/18/2025 | |

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| V 715 | <p>Continued From page 13</p> <p>heparin syringes when drawn up into a syringe to ensure it remained effective and safe to use for all patients prescribed heparin per their policy.</p> <p>Findings include:</p> <p>1. Observation on 4/1/25 at 10:50 a.m. in pod 2 revealed:</p> <ul style="list-style-type: none"> *Four syringes of heparin were on top of patient care supplies on the counter at the nurse's station. -The syringes of heparin had not been labeled with a time or the initials of the staff who prepared them. -The syringes of heparin were not secured. *Two heparin syringes hooked up to dialysis machines located in chairs 3 and 4 and infusing to patients (4 and 5) had not been labeled with the time or staff initials of who prepared them. <p>Interview and record review on 4/1/25 at 10:53 a.m. with charge nurse A revealed:</p> <ul style="list-style-type: none"> *Heparin syringes should have been labeled with the date, time, and the initials of the staff who had prepared the medication. *Heparin syringes and vials of heparin should have been kept secured and locked in drawers located in each pod. *Staff were expected to draw up heparin into syringes after the patients had arrived for their treatments. *Heparin should have been administered by the staff person who had prepared the medication. *She was unsure of how long heparin was effective or safe to use after it been drawn up into a syringe. *She stated, "I'm a traveling nurse and just started a few weeks ago. At my last job, heparin was good for six hours." | V 715 | | | |

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| V 715 | <p>Continued From page 14</p> <p>*She confirmed the provider's policy on the administration of heparin had not defined a timeframe of how long heparin was effective or safe to use after it had been drawn up in a syringe.</p> <p>Interview on 4/1/25 at 2:25 p.m. with director of dialysis B revealed:</p> <p>*Preprinted labels of heparin were prepared daily that included the patient's name, date, and dose of prescribed heparin.</p> <p>-Staff were expected to put the time and their initials on the preprinted label after the heparin was drawn up into a syringe.</p> <p>*Heparin should have been prepared at the time of the patient's arrival.</p> <p>*She was unsure of how long heparin was effective or safe to use after it had been drawn up into a syringe, but staff were to discard heparin at the end of the day.</p> <p>-She had reached out to the provider's corporate pharmacist for an answer.</p> <p>Review of the 2011 article provided by the corporate pharmacist labeled International Journal of Pharmaceutical Investigation revealed:</p> <p>*"Sterility</p> <p>-Once a standard syringe is filled with a medication, it will remain optimally effective, or sterile, for approximately 12 hours."</p> <p>Interview on 4/1/25 at 3:20 p.m. with registered nurse (RN) C revealed:</p> <p>*Staff were to use preprinted labels for heparin syringes.</p> <p>*Heparin syringes should have been labeled with the patient's name, drug, date, time, and the initials of the staff who prepared the medication.</p> <p>*He stated, "I believe when staff prepare the</p> | V 715 | | | |

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| V 715 | <p>Continued From page 15</p> <p>heparin syringes, they are placed in the patient's supply boxes."</p> <p>-The patient's supply boxes are not locked or secured.</p> <p>*He stated, "I don't consider heparin a medication, so it doesn't have to be locked."</p> <p>Interview on 4/1/25 at 3:30 p.m. with licensed practical nurse (LPN) D and E revealed:</p> <p>*Staff were to use preprinted labels for heparin syringes.</p> <p>*Heparin syringes should have been labeled with the patient's name, drug, time, date, and the initials of the staff who prepared the medication.</p> <p>*LPN's D and E stated that heparin that was drawn up in a syringe and was not hooked up to the dialysis machine within one hour, should have been discarded and not used.</p> <p>*They confirmed the staff who prepared the medication, should have been the staff who administered the medication to the patient.</p> <p>*They confirmed heparin was a medication and should have been secured.</p> <p>Interview on 4/2/25 at 7:40 a.m. with certified clinical hemodialysis technician (CCHT) F in pod 2 revealed:</p> <p>*Heparin was good for 12 hours once drawn up into a syringe.</p> <p>*She confirmed the staff who drew up the heparin into a syringe, should be the one who administered it.</p> <p>*She confirmed the expectation was for the heparin to be labeled with a preprinted label that contained the patient's name, drug, date, time, and the staff initials.</p> <p>*She stated, "I draw up the patient's heparin when they arrive, I don't prepare [the heparin] ahead of time."</p> | V 715 | | | |

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| V 715 | <p>Continued From page 16</p> <p>*She confirmed heparin was not to be stored in the patient's supply bins.</p> <p>*Heparin should have been secured in locked drawers.</p> <p>Interview on 4/2/25 at 7:52 a.m. CCHT G in pod 1 revealed:</p> <p>*He confirmed he would draw up the heparin into a syringe once the patient arrived.</p> <p>*He used the preprinted labels for heparin which included the patient's name, date, drug, dose, and the staff initials.</p> <p>*Heparin should have been prepared in a designated clean space away from patient stations.</p> <p>*Heparin vials should have been secured in a locked drawer.</p> <p>*He had not been aware of how long heparin was effective or safe to use after it had been drawn up into a syringe and available for patient use.</p> <p>Observation and interview on 4/2/25 at 8:35 a.m. with RN H at pod 3 revealed:</p> <p>*Three syringes containing heparin were lying on the counter at the nurse's station.</p> <p>-The syringes had not been secured.</p> <p>-The syringes were labeled with the patient's names, date, medication, staff initials and the following times: 8:07 a.m., 8:08 a.m., and 8:09 a.m.</p> <p>*She confirmed staff could have drawn up the heparin for administration and another staff could have administered it to a patient.</p> <p>-She stated, "The schedule can be hectic, we try to be proactive and help one another."</p> <p>*She confirmed:</p> <p>-The syringes had been drawn up and prepared for the patients expected to have been arriving at noon that day.</p> | V 715 | | | |

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| V 715 | <p>Continued From page 17</p> <p>-She thought heparin was good for four hours once drawn up into a syringe.</p> <p>-Their practice was not to secure or lock up the heparin.</p> <p>Interview on 4/2/25 at 8:45 a.m. with dialysis tech I revealed:</p> <p>*She stated, "I like to draw up the heparin ahead of time."</p> <p>*She stated:</p> <p>- "They say that it [heparin] is good for all day after it's drawn up [into a syringe].</p> <p>- I like to draw it up four hours ahead of time, be proactive, and help."</p> <p>*She confirmed she could have used the heparin prepared by another staff member.</p> <p>*Heparin should have been locked in a drawer and not sitting out unsecured on the counter.</p> <p>*She was new and her preceptor had been "okay" with her process described above.</p> <p>Interview on 4/2/25 at 8:50 a.m. with CCHT J revealed he:</p> <p>*Stated, "I did not receive much training regarding the provider's policy and procedures. It has been a rough transition."</p> <p>*He thought heparin was good for four hours but had relied on his former employer's policies to guide his practice.</p> <p>*Confirmed the above observations and stated he would have administered the heparin that had been drawn up by another staff member.</p> <p>*Confirmed heparin should have been secured and not left out on the counter.</p> <p>-Stated, "This has been a gray area here, they have not been clear on the direction."</p> <p>Interview on 4/2/25 at 9:15 a.m. with director of dialysis B revealed:</p> | V 715 | | | |

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| V 715 | <p>Continued From page 18</p> <p>*She confirmed heparin was a medication and it should have been secured in the designated areas located in each pod.</p> <p>*The staff who had drawn up the heparin should have been the staff who administered the heparin.</p> <p>*Staff should have been prepared the heparin when the patient arrived for dialysis.</p> <p>*Heparin should have been labeled with a preprinted label that contained the patient's name, medication, date, dose, time, and the staff initials.</p> <p>*Staff should have been educated on heparin administration.</p> <p>Interview on 4/3/25 at 8:30 a.m. with director of dialysis B confirmed there had been no written policy or guidance referencing the storage and securement of medications.</p> <p>Review of the provider's undated Administration and Use of Intravenous Heparin policy revealed:</p> <p>*"Heparin syringes will be labeled with all pertinent medication administration information listed.</p> <p>*Heparin will only be administered by the individual who prepared the medication.</p> <p>*All staff administering heparin must have documented education on the use of heparin in dialysis procedures.</p> <p>*All staff administering heparin will have a completed skills checklist reflecting mastery of medication administration (including heparin).</p> <p>*Procedure:</p> <p>-Label the syringe with patient name, time, contents, date, and initials of person preparing the med.</p> <p>-Once patient has been assessed, heparin will be administered by the person who prepared</p> | V 715 | | | |

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| V 715 | <p>Continued From page 19 medication."</p> <p>Review of the provider's undated Medication Administration Skills Checklist revealed: *"Verbalizes the nurse that prepares the medication is the nurse who administers the medication. *Medication is not prepared prior to patient arrival. *Medication syringe/cup labeled: -Drug -Dosage -Patient -Staff initial -Time prepared *Returns medications to a locked cabinet/refrigerator when not using. "Medication is not left at station or unsecure area."</p> <p>Review of the provider's undated Skills Checklist for Drawing up Heparin revealed: *"Labels syringe with patient's name, drug name, dose/volume, date, time, [staff] initials. -Preprinted labels will have all the medication information and will require documentation of date, time and [staff] initials when prepared."</p> <p>Review of the provider's November 2021 education on Heparin and Labs revealed: *"According to Corporate policy #303-Docmentation & Accountability for the Accuracy of Medication Administered and Billed, this is the process that should be followed drawing up and administering medications: -Label the syringe (patient's name, drug name, strength of drug, date and time) before administration unless walking directly to the patient's machine and administering the individual dose without putting down the syringe at any time.</p> | V 715 | | | |

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| V 715 | Continued From page 20 -The person who drew up the medication into the syringe will administer the medication in the syringe. -Prepare doses as close as possible to the time of use. -Label the syringe with patient name, time, contents, date, and initials of person preparing the medication." | V 715 | | | |