

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

PRINTED: 04/15/2025  
FORM APPROVED  
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER  152626		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 03/28/2025	
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE ELWOOD				STREET ADDRESS, CITY, STATE, ZIP COD 1805 S ANDERSON ST ELWOOD, IN 46036			
(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
E 0000  Bldg. 00	<p>An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62.</p> <p>Survey Dates: 03/26/2025 - 03/28/2025</p> <p>Active Census: 27</p> <p>At this Emergency Preparedness survey, Fresenius Medical Care Elwood was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.</p> <p>QR Completed on 04/02/2025 by A4</p>			E 0000			
V 0000  Bldg. 00	<p>This visit was for a CORE Federal recertification survey of an ESRD provider.</p> <p>Survey Dates: 03/26/2025 - 03/28/2025</p> <p>Census by service type:</p> <p>In-center Hemodialysis: 27</p> <p>Total active census: 27</p> <p>Isolation room / Waiver: Opened prior to 02/09/2009</p> <p>Abbreviations:</p>			V 0000			

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

TITLE

(X6) DATE

Kerrey Thornton

Director of Operations

04/14/2025

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 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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V 0113  Bldg. 00	<p>RN Registered Nurse PCT Patient Care Technician CVC Central Venous Catheter</p> <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE</p> <p>Based on observation, record review, and interview, the facility failed to ensure staff remove gloves and wash hands between each patient for 1 of 3 PCTs observed. (PCT 1)</p> <p>Findings include:</p> <p>1. According to the "Hand Hygiene" policy (Version 8, 11/06/2023), staff must decontaminate using an alcohol-based hand rub or by washing with antimicrobial soap and water before and after direct contact with patients.</p> <p>2. During an observation on 03/26/2025 at 11:14 AM, PCT 1 was observed pulling the fistula needles for a patient sitting in Station #11. Once the needles were removed, PCT 1 walked over to Station #12 to retrieve the phone from the floor that was dropped by the patient in Station #12 and hand it to him/her. PCT 1 failed to remove her gloves and sanitize her hands prior to touching another patient's belongings.</p> <p>3. During an interview on 03/28/2025 at 11:10 AM, PCT 1 indicated she should have removed her gloves and performed hand hygiene prior to picking up another patient's cell phone from the floor after cannulating a patient in another station. PCT 1 recognized her mistake immediately.</p>			V 0113	<p><b>V113 IC-WEAR GLOVES/HAND HYGIENE CFR(s): 494.30(a)(1)</b></p> <p>On 4/16/2025, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Hand Hygiene Emphasis will be placed on: Hand hygiene includes either washing hands with soap and water or using a waterless alcohol-based antiseptic hand rub with 60-90% alcohol content when: Hands are visibly dirty or contaminated with proteinaceous material, blood, or other body fluids Before and after direct contact with patients Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medication Immediately after removing gloves After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly</p>		04/27/2025

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			<p>soiled</p> <p>After contact with inanimate objects near the patient</p> <p>When moving from a contaminated body site to a clean body site of the same patient</p> <p>Effective 4/16/2025, Director of Operations or Designee will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring hand hygiene is done using soap and water or waterless alcohol-based antiseptic hand rub when hands are visibly dirty, before and after contact with patients, before performing any invasive procedure, immediately after removing gloves, after contact with body fluids, after contact with inanimate objects near patient and when moving from a contaminated body site to a clean body site of the same patient. The audits will then go to weekly for an additional 2 weeks or until 100% compliance is achieved.</p> <p>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. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The Director of Operations is</p>		

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			<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 04/27/2025.</p>		

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V 0114  Bldg. 00	<p>494.30(a)(1)(i) IC-SINKS AVAILABLE</p> <p>Based on observation, record review, and interview, the facility failed to dedicate a clean sink for hand washing, dedicate a utility sink for contaminated items and supply soap and paper towels at each clean sink in 1 of 1 facility observed.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. According to the "Hand Hygiene" policy (Version 8, 11/06/2023), hand washing sinks must have soap and a supply of paper towels protected from contamination that are available at each sink for patient and staff use. Used items should not be placed, cleaned, or drained in the hand washing sink.</li> <li>2. During an observation on 03/26/2025 at 9:51 AM, the clean sink located near the employee entrance to the treatment floor failed to house paper towels and hand soap necessary for proper handwashing.</li> <li>3. During an observation on 03/26/2025 at 9:51 AM, clean sink #1 failed to house hand soap and paper towels necessary for appropriate handwashing.</li> <li>4. During an observation on 03/26/2025 at 10:55 AM, the clean sink located in the laboratory area, sink #2, failed to house hand soap and paper towels to complete appropriate handwashing. A plastic tote labeled 1:100 bleach solution sat on the edge of the sink, where it was used to disinfect dirty clamps.</li> </ol>			V 0114	<p><b>V114 IC-SINKS AVAILABLE</b> <b>CFR(s):494.30(a)(i)</b> On 4/16/2025, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Hand Hygiene</p> <p>Emphasis will be placed on: A sufficient number of sinks with soap and plumbed with both hot and cold water shall be available to facilitate hand washing. The hand washing sinks may be used for both staff and patients. Soap and a supply of paper towels protected from contamination must be available at each sink. Hand washing sinks should be dedicated for hand washing only and should remain clean. Used items should not be placed, cleaned or drained in the hand washing sink. Sinks will be properly labeled for use.</p> <p>By 4/16/2025 the Director of Operations, will ensure all clean sinks has soap and paper towels stocked and all sinks are appropriately labeled for use. Effective 4/16/2025, Director of Operations will conduct 3 days per week audits, utilizing the facility</p>		04/27/2025

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	<p>5. During an interview on 03/26/2025 at 9:53 AM, PCT 2 indicated that staff should ensure hand soap and paper towels are available at the clean sinks for handwashing.</p> <p>6. During an interview on 03/26/2025 at 12:03 PM, RN 1 indicated the clean sink located in the laboratory station was used only for disinfection of dirty clamps and not used for handwashing. She expressed uncertainty whether hand soap and paper towels were required at clean sinks.</p>		<p>specific audit tool, with focus on ensuring soap and paper towels are available at all clean sinks and all sinks are appropriately labeled for use, for 2 weeks and then weekly for an additional 2 weeks or until 100% 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.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The Director of Operations 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.</p> <p>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.</p> <p>The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to</p>		

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V 0122  Bldg. 00	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL</p> <p>Based on observation, record review, and interview, the facility failed to maintain procedures in cleaning and disinfection of contaminated surfaces, medical devices, and equipment during 3 of 3 observations of dialysis station disinfections. (Station #2, #7, &amp; #10)</p> <p>Findings include:</p> <p>1. According to the "Cleaning and Disinfecting the Dialysis Station" policy (Version 14, 09/05/2023), non-disposable equipment in the dialysis station, including the wall box, must be disinfected with 1:100 bleach or EPA-registered disinfectant between each patient.</p> <p>2. During an observation on 03/26/2025 at 10:05</p>	V 0122	<p>develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly.</p> <p>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.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 04/27/2025.</p> <p><b>V122 IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTCOL CFR(s): 494.30(a)(4) (ii)</b></p> <p>On 4/16/2025, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Cleaning and Disinfecting the Dialysis Station Emphasis will be placed on: After use, any non-disposable equipment and supplies brought into the dialysis station (ex. Stethoscope) must be disinfected</p>	04/27/2025	

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	<p>AM, PCT 3 failed to disinfect the inside of the prime container located on the dialysis machine and failed to disinfect the wall box and counter prior to starting a new treatment in Station #7.</p> <p>3. During an observation on 03/26/2025 at 10:30 AM, PCT 2 removed fluid from the prime waste container and returned it to the dialysis machine without disinfecting the internal surface of the prime waste container in Station #2.</p> <p>4. During an observation on 03/26/2025 at 10:30 AM, PCT 2 failed to clean the counter and wall box behind the dialysis chair as part of cleaning the station after the patient had vacated Station #2.</p> <p>5. During an observation on 03/26/2025 at 10:56 AM, PCT 3 failed to disinfect the wall box and counter behind the dialysis station prior to starting a new treatment in Station #10.</p> <p>6. During an interview on 03/28/2025 at 9:53 AM, RN 1 indicated that when cleaning dialysis stations between patients and at the end of the day the back wall does not get disinfected unless visibly soiled.</p> <p>7. During an interview on 03/28/2025 at 11:30 AM, PCT 3 indicated that the back wall and inside of the prime container should be disinfected after each patient.</p>				<p>with 1:100 bleach or EPA registered disinfectant before being removed from the dialysis station.</p> <p>Dialysis wall boxes and the area/wall around the wall box must be routinely cleaned at the end of each treatment day or immediately if splattered with blood. All surfaces shall be surface disinfected with 1:100 bleach solution. Special attention should be given to removing build-up and/or cleaning splatter and spray of concentrate solution. If concentrate leaks are noted at the wall box, staff should notify biomedical services for repair.</p> <p>Effective 4/16/2025, the Director of Operations will conduct 3 days per week audits, for 2 weeks utilizing the facility specific audit tool, with focus on ensuring all non-disposable equipment in the dialysis station to include but not limited to the prime waste bucket and the wall box and shelf behind the machine and patient chair is disinfected after each patient treatment with 1:100 bleach solution, and then weekly for an additional 2 weeks or until 100% 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.</p>		

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			<p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The Director of Operations 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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The QAPI and Governing Body minutes, education and monitoring</p>		

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V 0147  Bldg. 00	<p>494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE</p> <p>Based on observation, record review, and interview, the facility failed to ensure adequate infection control procedures were performed to prevent CVC infections on 2 of the 2 CVCs observed. (Patient #6, and #8)</p> <p>Findings include:</p> <p>1. According to the "Changing the Catheter Dressing Procedure" policy (Version 8, 02/05/2024), staff should use 2% Chlorhexidine (a skin disinfectant) using a gentle back and forth friction cleaning the exit site. Cleaning of the exit site should begin in the center and continuing outward in a concentric circle the size of the dressing to be applied for 30 seconds.</p> <p>2. According to the "Initiation of Treatment Using a Central Venous Catheter (CVC) and Optiflux Single Use Ebeam Dialyzer" policy (Version 8, 05/06/2024), staff should use a sterile alcohol pad to scrub the threads and end of the hub of the CVC thoroughly with friction for 10 - 15 seconds, making sure to remove any residue.</p> <p>3. According to the "Reversal of Central Venous Catheter Lines" policy (Version 1, 02/05/2024), the RN assesses, performs, and troubleshoots procedures to reverse CVC lines as part of their responsibilities and scope of practice.</p>			V 0147	<p>documentation, are available for review at the clinic.</p> <p>Completion Date: 04/27/2025.</p> <p><b>V147 IC- STAFF EDUCATION-CATHETER CARE CFR: 494.3</b></p> <p>On 4/16/2025, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Changing the Catheter dressing procedure Initiation of Treatment Using a Central Venous Catheter (CVC) and Optiflux Single Use Ebeam Dialyzer Reversal of Central Venous Catheter Lines</p> <p>Emphasis will be placed on: Follow the steps below to remove a catheter dressing and inspect the exit site before the initiation of dialysis treatment. Place an underpad under catheter limbs to protect work area and clothing. Apply mask to patient and caregiver to help prevent contamination by airborne nasal bacteria. Perform hand hygiene. Don clean gloves.</p>		04/27/2025

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	<p>4. During an observation on 03/26/2025 at 12:03 PM, PCT 3 completed CVC exit site care for Patient #6. After removing the old exit site dressing, PCT 3 disinfected the site using Chlorhexidine for 7 seconds. PCT 3 failed to disinfect the CVC exit site for 30 seconds.</p> <p>5. During an observation on 03/26/2025 at 12:11 PM, PCT 1 completed CVC exit site care for Patient #8. After removing the old exit site dressing, PCT 1 disinfected the site using Chlorhexidine for 7 seconds. PCT 1 failed to disinfect the CVC exit site for 30 seconds.</p> <p>6. During an observation on 03/26/2025 at 12:03 PM, PCT 3 initiated the dialysis treatment for Patient #6. The CVC hubs were disinfected with an alcohol pad for 5 &amp; 7 seconds. PCT 3 failed to disinfect the CVC hubs for 10-15 seconds.</p> <p>7. During an observation on 03/26/2025 at 12:17 PM, PCT 1 was unable to pull blood from the arterial line of the CVC for Patient #8. RN 1 was notified but failed to assess the malfunctioning CVC prior to instructing PCT 1 to reverse the lines and begin treatment.</p> <p>8. During an interview on 03/28/2025 at 9:45 AM, RN 1 indicated that staff should scrub CVC hubs with alcohol pads for at least 15 seconds and scrub the exit site with chlorhexidine for at least 30 seconds.</p> <p>9. During an interview on 03/28/2025 at 9:53 AM, RN 1 stated that she believes nurses should perform assessments, although she usually relies on the PCTs and does not conduct them herself.</p>		<p>Inspect and remove the old dressing. Check to see if dressing looks visibly soiled with exudate or blood.</p> <p>Visually inspect the exit site and surrounding area. Observe for signs and symptoms of infection or complications such as: · redness · swelling · tenderness · drainage at the exit site · thinning or wearing away of the skin, · cuff extrusion · dislodgement of catheter</p> <p>Notify team leader, charge nurse or home therapy nurse if any of the following are present:</p> <p>Any signs or symptoms as outlined in step 6 · Change in the position or appearance of the catheter · Dressing visibly soiled with exudate or blood</p> <p>Perform hand hygiene and don clean gloves.</p> <p>Remove swabstick from package by stick end without touching foam applicator. Handle only the stick portion.</p> <p>2% Chlorhexidine and 70% alcohol: Using gentle back and forth friction, clean the exit site beginning in the center and continuing outward the area of the size of the dressing to be applied (2 inches) in a concentric circle for 30 seconds and allow to dry a minimum of 30 seconds. If exudate or crusting is noted, an additional swabstick may be necessary to clean the exit site.</p> <p>Using aseptic technique, apply</p>		

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			<p>the catheter dressing over dry exit site, being careful not to touch the patient side of the dressing with gloved hands or to any surface.</p> <p>The following steps should be followed prior to initiating treatment with a Central Venous Catheter:</p> <p>Perform hand hygiene and don full PPE</p> <p>Place an under pad under the access limbs to protect the work area and the patient's clothing.</p> <p>Check to make sure catheter clamps are closed.</p> <p>Remove cap from clamped arterial limb</p> <p>Using a sterile alcohol pad (or other antiseptic such as chlorhexidine, povidone if required by the hospital) scrub the sides (threads) and end of the hub thoroughly with friction, making sure to remove any residue.</p> <p>Using the same sterile alcohol pad (or other antiseptic such as chlorhexidine, povidone if required by the hospital) applying friction to remove any blood or residue, move from the hub at least several centimeters towards the body of the catheter. (Steps 3 and 4 should take 10-15 seconds.)</p> <p>Hold the limb while allowing the antiseptic to dry</p> <p>Attach a sterile empty 10 mL syringe to limit exposure to air. Repeat steps 1-6 for venous catheter limb.</p>		

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			<p>It is the RNs responsibility and scope of practice to evaluate and correct CVC dysfunction. The RN should NEVER direct PCTs LPN / LVNs, patient or care partners to evaluate or correct CVC dysfunction. The RN is responsible for assessing and performing any trouble-shooting procedures including reversal of CVC lines.</p> <p>Effective 4/16/2025, Director of Operations will conduct 3 days per week audits for 2 weeks utilizing the facility specific audit tool, with focus on ensuring the FKC policy for Central Venous Catheter (CVC) dressing change procedure is followed as lined out above. Focus will also be on ensuring that the preparation of the CVC hubs prior to dialysis initiation will be completed following the FKC policy as outlined above, as well as ensuring the RN is the one evaluation and correcting CVC dysfunction, the audits will then go to weekly for an additional 2 weeks or until 100% compliance is achieved.</p> <p>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. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p>		

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			<p>The Director of Operations 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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 04/27/2025.</p>		

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V 0507  Bldg. 00	<p>494.80(a)(4) PA-ASSESS ANEMIA</p> <p>Based on record review and interview, the facility failed to follow physician orders related to anemia for 1 of 5 patients reviewed. (Patient #4)</p> <p>Findings include,</p> <p>According to a facility algorithm revised 09/07/2017, titled, "Corporate MAB Recommended Anemia Algorithm Mircera IVP Administration (InCenter Only) Version 4.0" Mircera (a medication used to treat anemia) is generally administered every two weeks or less frequently and dosing is tied to the patient's hemoglobin result.</p> <p>A document titled, "Patient Transfer: Care Transitions Report" for Patient #4 indicated a Hemoglobin (protein found in red blood cells that carry oxygen throughout the body and a lab result used to dose Mircera) result of 7.0 on 3/11/2025, 6.9 on 3/18/2025, and 9.1 on 3/25/2025.</p> <p>The clinical record for Patient #4 was reviewed and evidenced the following:</p> <p>A 03/08/2025 physician order indicated administration of Mircera every 2 weeks.</p> <p>A treatment sheet dated 03/13/2025 indicated the last dose of Mircera was administered on 01/25/2025.</p> <p>A treatment sheet dated 03/14/2025 indicated a dose of Mircera was administered.</p> <p>A 03/18/2025 physician order indicated</p>			V 0507	<p><b>V507 PA-ASSESS ANEMIA CFR(s): 494.80(a)(4)</b></p> <p>On 4/16/2025, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Corporate MAB Recommended Anemia Algorithm Mircera IVP Administration (InCenter Only)</p> <p>Emphasis will be placed on:</p> <p>Mircera is generally administered every two weeks or less frequently, and dosing is tied to the patient's hemoglobin result.</p> <p>If a dose of Mircera is not administered on the scheduled dosing day, administer the missed dose within 3 days.</p> <p>If unable to administer Mircera within the 3 days, then administer Mircera at the next dosing day per the Lab Draw/Dose Administration schedule.</p> <p>Revise the patient's active Mircera order per the dosing schedule based upon the patient's: Current Spectra Hgb result within 7 days and Mircera order frequency.</p> <p>At least 11 days must elapse since the patient's last dose of Mircera</p> <p>Effective 4/16/2025, Director of</p>		04/27/2025

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	<p>administration of Mircera once.</p> <p>A treatment sheet dated 03/18/2025 indicated administration of a one-time dose of Mircera by RN 1.</p> <p>During an interview on 03/28/2025 at 9:12 AM, RN 1 indicated on 03/18/2025 a verbal order was obtained for Patient #4 to administer Mircera as a one-time order due to the previous order on 03/08/2025 not being administered. RN 1 was unsure why the 03/08/2025 Mircera dose was not administered as ordered but could not find it as being administered in the clinical record. RN 1 indicated that the electronic clinical record did not reflect this as completed or given and is unsure how this had happened. RN 1 indicated that Mircera should be administered no more frequently than every 2 weeks unless otherwise specified by the physician and indicated the physician was called and advised the previous dose was missed, thus obtaining a one-time order.</p>				<p>Operations will conduct 3 days per week audits for 2 weeks utilizing the facility specific audit tool, with focus on ensuring the Mircera administration is followed per the above listed algorithm with a focus on ensuring at least 11 days elapse between Mircera doses, the audits will then go to weekly for an additional 2 weeks or until 100% 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. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The Director of Operations 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.</p> <p>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.</p> <p>The QAPI Committee is responsible to provide oversight,</p>		

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V 0715  Bldg. 00	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&amp;P</p> <p>Based on observation, record review, and interview, the medical director failed to ensure staff followed policies and procedures to include appropriate labeling and storage of medications for 1 of 1 facility reviewed, physician orders for blood pressure (BP) monitoring for 2 of 5 patient records reviewed (Patient #1, 2), and assessment of the fistula on 1 of 2 patients observed (Patient #7).</p> <p>Findings include:</p> <p>Unsecured Medications</p>	V 0715	<p>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.</p> <p>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.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 04/27/2025.</p> <p><b>V715 IC: MD RESP-ENSURE ALL ADHERE TO P&amp;P CFR: 494.150</b> On 4/16/2025, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Medication preparation and administration Patient Assessment and Monitoring Access Assessment and Cannulation Emphasis will be placed on: All medications in syringes</p>	04/27/2025	

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	<p>1. According to the "Medication Preparation and Administration" policy, (Version 9, 02/06/2023), all medications in syringes not being administered immediately shall be labeled with name of medication, route, dose, name of patient, date, time, and initials of the person who prepared the medication. All medications will be kept in a locked cabinet except when they are in use.</p> <p>2. During an observation on 03/26/2025 at 9:40 AM, four pre-filled syringes labeled Heparin (a medication used to prevent clotting of blood) were in an unsecured drawer located in the middle of the treatment floor. The pre-filled syringe labels failed to evidence the time and staff member that drew up the medication.</p> <p>3. During an observation on 03/26/2025 at 12:01 PM, two opened vials of Heparin were sitting on the medication counter unsecured. PCT 1 completed drawing up the medication and left it unattended to initiate a treatment.</p> <p>4. During an observation on 03/28/2025 at 11:45 AM, PCT 1 was observed drawing up Heparin. PCT 1 retrieved the keys from the medication refrigerator using a code to open the door. This medication refrigerator housed medications to treat anemia, Mircera, as well as vaccinations. Once the medication was drawn, PCT 1 returned the keys to the refrigerator using a code to open the door.</p> <p>5. During an interview on 03/26/2025 at 9:53 AM, PCT 3 indicated she had drawn up the Heparin for her incoming patients and secured them in the drawer, so they were out of sight of the patients. She indicated she could not find a locked cabinet or drawer to secure the medications and acknowledged that she should have written her</p>				<p>not being administered immediately shall be labeled appropriately with the name of the medication, route, dose, name of patient, date, time and initials of the person who prepared the medication. If more than one syringe of the same medication is needed for a single patient, mark the label as "1 of 2, 2 of 2."</p> <p>Medications may be pre-drawn up to 4 hours prior to administration. These pre-drawn medications shall be labeled and must be kept under the preparer's control or in a locked designated medication storage area or refrigerated, if necessary, until delivery to the appropriate patient for administration.</p> <p>The following steps must be taken for the securement: All medications will be kept in a locked cabinet except when in use. One key to the medication cabinet will be kept by the charge nurse/team leader. The Clinical Manager will retain a spare key, kept in a secure location. The key to the medication cabinet will be kept in a secure location when the facility is closed. Only the clinical manager, charge nurse and team leader will have access to the location. When the charge nurse/ team leader leaves the treatment area, the key will be left in the</p>		

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	<p>initials and time on the labels at the time of preparation.</p> <p>6. During an interview on 03/26/2025 at 10:22 AM, PCT 3 indicated she had discarded the Heparin she had previously drawn, and redrew new Heparin syringes with the appropriate labeling, time, and staff initials.</p> <p>7. During an interview on 03/26/2025 at 12:03 PM, RN 1 indicated that staff can draw up all pre-drawn medications 4 hours prior to administration. The label must contain the time the medications were prepared and initials of the staff member who prepared it. RN 1 further indicated being unaware of facility policy regarding securement of medications. She stated that she opens the medications cabinets in the morning and locks them up prior to leaving for the day. After checking the policy, RN 1 indicated that all medications are to be secured when not in use.</p> <p>8. During an interview on 03/28/2025 at 11:51 AM, RN 1 indicated that the medication refrigerator stores Mircera and vaccinations along with the keys to the medication cabinets. She was unsure if PCTs could have access to these medications. The keys to the medication cabinets are not kept with the nurse as they could be easily lost.</p> <p>9. During an interview on 03/28/2025 at 12:03 PM, PCT 1 indicated the medication refrigerator housed the keys to the medication cabinets along with medications that nurses administer.</p> <p>Patient assessment and monitoring</p> <p>1. According to the "Patient Assessment and Monitoring" policy (Version 4, 05/01/2023) direct</p>				<p>possession of other qualified, licensed personnel.</p> <p>Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations.</p> <p>Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulation</p> <p>Check prescribed blood flow is being achieved or reason is documented in medical record if unable to meet prescribed blood flow.</p> <p>Follow the steps below to assess the vascular access:</p> <p>LOOK:</p> <p>Skin</p> <p>Discoloration/Redness/Bruising/Le sion</p> <p>Hematomas</p> <p>Extremity or Other Swelling</p> <p>New or change in aneurysm or pseudoaneurysm</p> <p>Poor rotation of cannulation sites</p> <p>Pus</p> <p>Greater than Expected Redness</p> <p>Greater than Expected Swelling</p> <p>Any other unusual findings</p> <p>Document in treatment record.</p> <p>LISTEN:</p> <p>Bruit high pitch/whistle</p> <p>Bruit not present throughout access Click here to link to Sound Clips</p> <p>Document in treatment record.</p>		

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	<p>patient care staff obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes.</p> <p>2. A clinical record for Patient #1 was reviewed and evidenced the following:</p> <p>A treatment sheet dated 03/05/2025 for Patient #1 indicated a blood pressure (BP) &amp; pulse check completed at 11:34 AM with a subsequent BP &amp; pulse check completed at 12:32 PM.</p> <p>3. A clinical record for Patient #2 was reviewed and evidenced the following:</p> <p>A treatment sheet dated 03/24/2025 for Patient #2 indicated a BP &amp; pulse check completed at 7:31 AM with a subsequent BP &amp; pulse check completed at 8:39 AM.</p> <p>A treatment sheet dated 03/24/2025 for Patient #2 indicated a BP &amp; pulse check completed at 9:05 AM with a subsequent BP &amp; pulse check completed at 10:01 AM.</p> <p>A treatment sheet dated 03/26/2025 for Patient #2 indicated a BP &amp; pulse check completed at 7:07 AM with a subsequent BP &amp; pulse check completed at 8:04 AM.</p> <p>4. During an interview on 03/28/2025 at 9:45 AM, RN 1 indicated that staff should do blood pressure checks every 30 minutes and more frequently if necessary.</p> <p>5. During an interview on 03/28/2025 at 11:30 AM, PCT 3 indicated that staff should conduct BP checks every 30 minutes, more frequently if necessary, and report any abnormalities to the nurse.</p>				<p>NOTE: Staff/patients/care partners who have been trained to auscultate vascular accesses should listen to the entire length of the access for changes in the sound of the bruit – a normal low-pitched bruit should be present.</p> <p>Clean stethoscope after assessing a patient.</p> <p>If direction of flow is not documented in the patient's medical record, compress in the middle of the access and listen to both ends. The arterial end will still be receiving blood flow and a bruit will be present. The venous side will have no sound because you have interrupted flow with your finger temporarily.</p> <p>If no sounds present, assume the access is thrombosed and do not attempt cannulation. Nurse will communicate with physician for referral to interventionalist/surgeon.</p> <p>FEEL:</p> <p>Pulse not soft/not easily compressible</p> <p>Thrill not strong at anastomosis</p> <p>Thrill not present throughout access</p> <p>Document in treatment record. Effective 4/16/2025, Clinical will conduct 3 days per week audits, for 2 weeks, utilizing the facility specific audit tool with focus on ensuring all pre-filled syringes are kept secured in a locked cabinet or drawer until time of</p>		

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	<p>AVF Assessment and Cannulation</p> <p>1. According to the "Access Assessment and Cannulation" policy (Version 4, 05/06/2024), the internal access must be assessed for patency, signs of infection, and any abnormal findings with the Look, Listen, Feel method.</p> <p>2. During an observation on 03/26/2025 at 10:29 AM, PCT 3 initiated Patient #7's Arterial Venous Fistula (AVF) to start treatment. PCT 3 failed to listen to the patient's AVF prior to cannulation (inserting the needles).</p> <p>3. During an interview on 03/28/2025 at 9:53 AM, RN 1 indicated that staff should assess fistula sites by visually inspecting the site, feeling for the thrill, and listening with a stethoscope to detect the bruit.</p> <p>4. During an interview on 03/28/2025 at 11:30 AM, PCT 3 indicated that before canulation of a fistula staff should look at the site, feel for the thrill, and listen for the bruit with a stethoscope.</p>				<p>administration and the label will include initials of person who prepared syringe. A focus will also be on ensuring the medications are secured in a locked cabinet and the key will be kept in the procession of the license staff member or in a secured location only accessible by licensed staff. A focus will be . A focus will also be on ensuring the patient access is assessed prior to cannulation by the above outlined Look, Listen and Feel procedures. A focus will also be on ensuring blood pressure and machine parameters are obtained and documented every 30 minutes but not to exceed 45 minutes, the audits will then go to weekly for an additional 2 weeks or until 100% 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. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The Director of Operations 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.</p>		

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

PRINTED: 04/15/2025

FORM APPROVED

OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER  152626		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 03/28/2025	
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE ELWOOD				STREET ADDRESS, CITY, STATE, ZIP COD 1805 S ANDERSON ST ELWOOD, IN 46036			
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					<p>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.</p> <p>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.</p> <p>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.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 04/27/2025.</p>		