

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152576	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 05/29/2025
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE FORT WAYNE DUPONT		STREET ADDRESS, CITY, STATE, ZIP COD 10204 E DUPONT CIRCLE DR FORT WAYNE, IN 46825		
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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: May 27, 28, and 29, 2025</p> <p>Active Census: 46</p> <p>At this Emergency Preparedness survey, Fresenius Medical Care Fort Wayne Dupont was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.</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: May 27, 28, and 29, 2025</p> <p>Census by Service Type:</p> <p>In-Center Hemodialysis: 46</p> <p>Total Active Census: 46</p> <p>Isolation Room/Waiver: Waiver dated February 15, 2022</p> <p>Abbreviations:</p> <p>RN Registered Nurse</p> <p>CVC Central Venous Catheter</p> <p>PCT Patient Care Technician</p> <p>ICHD In-Center Hemodialysis</p>	V 0000		

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

TITLE

(X6) DATE

Allison Cruea

Director of Operations

06/13/2025

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosed 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 0111 Bldg. 00	<p>QR 6/2/25 A2</p> <p>494.30 IC-SANITARY ENVIRONMENT</p> <p>Based on observation, policy review, and interview, the dialysis facility failed to maintain a sanitary environment specific to the preparation of bleach solution for 1 of 1 observations of bleach solution mixing, which had the potential to affect 46 active patients.</p> <p>Findings include:</p> <p>1. The "Mixing Bleach" policy, dated 02/03/2025, indicated a 1:10 concentration would be made with 1 part bleach to 9 parts water (10% bleach and 90% water). A 1:100 concentration would be made with 1 part bleach to 99 parts water (1% bleach and 99% water). The policy indicated when mixing the bleach solution, staff should measure water and bleach to ensure proper concentration.</p> <p>2. During an observation on 5/28/25 at 4:24 AM, Charge Nurse 3 mixed bleach solution to be used on the ICHD treatment floor. The nurse mixed 3,000 milliliters (mL) water and 30 mL of bleach into two containers labeled 1:100 bleach solution, resulting in a bleach concentration of 0.9%. Charge Nurse 3 also mixed 900 mL water and 30 mL of bleach into one container labeled 1:10 bleach solution, resulting in a total bleach concentration of 3.2%.</p> <p>Review of the labels on containers used to store the bleach solution evidenced the following:</p> <p>a. A label on the two 1:100 bleach solution containers indicated the solution was to be made</p>		V 0111	<p>On 5/30/2025, the Facility Administrator (FA) held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>§ Mixing Bleach</p> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> · Diluting a bleach solution to: <ul style="list-style-type: none"> o 1:100 = 1 part bleach to 99 parts water o 1:10 = 1 part bleach to 9 parts water. · Pour the measured amount of water needed into a labeled opaque container. Measuring ensures proper concentration: <ul style="list-style-type: none"> · 1:100 = 1-part bleach + 99 parts water · 1:10 = 1-part bleach + 9 parts water. · Slowly pour the measured amount of bleach into measured water in opaque container. Mix solution. Mixing slowly decreases fumes. · Label opaque container with "Bleach Solution", strength of solution, date and time prepared, and preparer's initials. <p>Effective 6/2/2025 the FA will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring the 1:10 and 1:100</p>

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	<p>by mixing 2,970 mL of water and 30 mL of bleach.</p> <p>b. A label on the 1:10 bleach solution container indicated the solution was to be made by mixing 270 mL of water and 30 mL of bleach.</p> <p>During an interview on 5/28/25 beginning at 10:14 AM, Charge Nurse 3 reported the 1:100 mL bleach solution was made with 3,000 mL water and 30 mL bleach. Charge Nurse 3 then reviewed the label on the 1:10 bleach solution container and reported the solution should be made with 270 mL water. When asked how the staff measure to 270 mL, the nurse reported staff use a Pyrex measuring cup to measure the water, which had a "thick" line immediately beneath the 300 mL mark. Charge Nurse 3 reported staff should fill the water this line to measure approximately 270 mLs.</p>			<p>bleach solution are properly measure by staff when mixing and properly labeled. 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 FA 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</p>	

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V 0113 Bldg. 00	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure infection control policies related to hand hygiene were followed for 1 of 2 PCTs observed who discontinued dialysis for patients with an arteriovenous fistula or graft (PCT 1).</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. The Hand Hygiene policy, revised 11/06/2023, indicated " ... Hands Will Be ... Decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water ... Before and after direct contact with patients ... After contact with inanimate objects near the patient ... After contact with other objects within the patient station or treatment space ... " 2. The Termination of Treatment Using an Arteriovenous Fistula or Graft policy, revised 11/04/2024, indicated " ... Disconnect the blood lines from the needle lines and remove the needles according to the Post Treatment Needle Removal Procedure ... " 3. The Post Treatment Fistula Needle Removal 		V 0113	<p>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: 06/29/2025.</p> <p>On 5/30/2025, the FA held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>§ Hand Hygiene</p> <p>§ Termination of Treatment Using an Arteriovenous Fistula or Graft and Optiflux® Single Use Ebeam Dialyzer</p> <p>§ Post treatment fistula needle removal procedure</p> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> · 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: <ul style="list-style-type: none"> o Hands are visibly dirty or contaminated with proteinaceous material, blood, or other body fluids o Before and after direct contact with patients o Before performing any invasive 	06/29/2025

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	<p>Procedure, revised 07/01/2024, indicated " ... The person removing needles will perform hand hygiene and don clean gloves ..."</p> <p>4. During a treatment floor observation on 05/27/2025 at 10:42 AM, PCT 1 reinfused the extracorporeal circuit and disconnected the blood lines aseptically for Patient #1. PCT 1 then removed one of the two needles without first performing hand hygiene and a glove change. PCT 1 failed to perform hand hygiene and don new gloves after touching the dialysis machine and before removing the first needle.</p> <p>5. During an interview on 05/29/2025 at 12:00 PM, PCT 1 indicated she wouldn't necessarily perform hand hygiene and don new gloves after touching the dialysis machine in the patient's station and before removing needles because it's the patient's machine.</p> <p>6. During an interview on 05/29/2025 at 12:03 PM, the Administrator indicated staff should perform hand hygiene and don new gloves after touching the dialysis machine in the patient's station and prior to needle removal.</p>		<p>procedure such as vascular access cannulation or administration of parenteral medication</p> <ul style="list-style-type: none"> o Immediately after removing gloves o After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled o After contact with inanimate objects near the patient o When moving from a contaminated body site to a clean body site of the same patient · Follow the steps below to prepare to remove the patient from the extracorporeal system: o Disconnect the blood lines from the needle lines and remove the needles according to the Post Treatment Needle Removal Procedure. o The person removing needles will perform hand hygiene and don clean gloves. <p>Effective 6/2/2025, the FA will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring hand hygiene is performed when removing gloves and also as listed above. A focus will also be on ensuring the steps above for needle removal are followed. The audits will then go to weekly for an additional 2 weeks or until 100% compliance is achieved.</p>	

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				<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 FA 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</p>

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V 0115 Bldg. 00	<p>494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK</p> <p>Based on observation, policy review, and interview, the dialysis facility failed to ensure staff did not consume food on the ICHD treatment floor for 1 of 2 days of ICHD floor observations (Charge Nurse 3).</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. The "General Cleanliness and Infection Control Guidelines" policy, dated 11/04/24, indicated staff were prohibited from eating in work areas "where there is reasonable likelihood of occupational exposure." 2. During an ICHD treatment floor observation on 5/28/25, the following was observed: <ol style="list-style-type: none"> a. At 5:52 AM, Charge Nurse 3 was in Station 5 while PCT 4 was performing CVC site care and initiating Patient #13's dialysis. The nurse was chewing gum in the station. b. At 6:17 AM, Charge Nurse 3 was in Station 1 while Patient #14 was receiving dialysis. The nurse was chewing gum in the station. 3. During an interview on 5/28/25 beginning at 10:14 AM, Charge Nurse 3 reported staff were not permitted to have food or drinks on the treatment floor, including gum. 		V 0115	<p>minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 06/29/2025.</p> <p>On 5/30/2025, the FA held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>§ General Cleanliness and Infection Control Guidelines</p> <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> · Eating, drinking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure. <p>Effective 6/2/2025, the FA will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring there is no eating or drinking in work areas where there is a reasonable likelihood of occupational exposure including but not limited to chewing gum.</p> <p>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.</p>	06/29/2025

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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 FA 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.</p> <p>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: 06/29/2025.</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, policy and procedure review, and interview, the dialysis facility failed to ensure staff performed appropriate infection control measures specific to CVC care for 1 of 2 CVC exit site care observations (Patient #13) and 1 of 2 CVC discontinuation of dialysis observations (Patient #13).</p> <p>Findings include:</p> <p>1. The "Changing the Catheter Dressing Procedure," dated 5/02/25, indicated when cleaning a CVC with Chloraprep (antiseptic solution comprised of 2% Chlorhexidine and 70% alcohol), staff should "clean the exit site beginning in the center and continuing outward ... in a concentric circle"</p> <p>2. The "Termination of Treatment Using a Central Venous Catheter ..." policy, dated 11/04/24, indicated prior to disconnecting a patient from dialysis, staff should "ensure that a clean under pad is below the catheter limbs to protect the work area and the clothing."</p> <p>During an interview on 5/28/25 beginning at 10:14 AM, Charge Nurse 3 reported when performing CVC exit site care, staff should clean with Chloraprep from the inside by the insertion point ("clean") towards the outside ("dirty") in circles.</p> <p>3. During an observation on 5/28/25 beginning at 6:36 AM, PCT 3 was in Station 3 performing exit site care to Patient #13's CVC. The technician cleaned the site using a Chloraprep swab around</p>		V 0147	<p>On 5/30/2025, the FA held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policies.</p> <ul style="list-style-type: none"> · Initiation of Treatment Using a Central Venous Catheter (CVC) and Optiflux Single Use Ebeam Dialyzer · Changing the Catheter Dressing Emphasis will be placed on: · Follow the steps below to prepare for the termination of dialysis: <ul style="list-style-type: none"> o Ensure that a clean under pad is below the catheter limbs to protect the work area and the clothing. · Follow the steps below to clean the catheter exit site: <ul style="list-style-type: none"> o Remove swabstick from package by stick end without touching foam applicator. Handle only the stick portion. 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. Effective 6/2/2025, the FA will 	06/29/2025

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	<p>the exit site in a concentric circle, then moved the swab back towards the exit site ("dirty" to "clean" area).</p> <p>4. During an observation on 5/28/25 beginning at 9:55 AM, PCT 3 was in Station 3 discontinuing Patient #13's dialysis. The technician failed to place a clean under pad under the CVC prior to disconnecting Patient from dialysis.</p> <p>5. During an interview on 5/28/25 beginning at 1:19 PM, PCT 3 reported when performing CVC exit site care, he would clean with a Chloraprep swab from the outside (dirty) in towards the exit site (clean). When discontinuing a patient from dialysis with a CVC, the technician reported he would only place a clean under pad if the current under pad was visibly soiled.</p>			<p>conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring a clean under pad is placed under the catheter lumens prior to discontinuing treatment and that when the catheter exit site is disinfected a gentle back and forth friction is used in a concentric circle for 30 seconds. 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 FA 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</p>

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V 0230 Bldg. 00	494.40(a) MIXING SYSTEMS-CLEANING Based on observation, manufacturer's instructions, and interview, the dialysis facility failed to ensure staff performed post-bleach testing of the bicarbonate distribution tank according to manufacturer's instructions for 1 of 1 observation of ICHD treatment floor opening procedures, which had the potential to affect 46 active patients. Findings include: 1. Manufacturer's instructions for RPC Ultra-Low Total Chlorine Test Strips indicated when performing a total chlorine test, staff should remove the test strip from the solution, shake the strip once "to remove excess water," then wait 20 seconds for the test strip color to develop before reading the result.		V 0230	<p>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: 6/29/2025</p> <p>On 5/30/2025, the FA held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <ul style="list-style-type: none"> · Total Chlorine Testing using RPC Ultra Low Total Chlorine Test Strips Procedure Emphasis will be placed on: · After collecting the sample and following steps in RPC strip testing wait 20 seconds for the test strip color to develop. While waiting, fold the white plastic handle of the test strip under the reagent area aperture so that it provides a consistent viewing background. · After the 20 second wait period, 	06/29/2025

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	<p>2. During an observation of ICHD treatment floor opening procedures on 5/28/25 beginning at 3:42 AM, PCT 3 reported the bicarbonate system was bleached at the end of the 5/27/25 shift, and the bicarbonate concentrate would need to be tested for residual bleach. After preparing the bicarbonate batch, PCT 3 transferred the solution to the distribution tank and drew a sample to check for bleach. PCT 3 dipped the Total Chlorine test strip in the bicarbonate sample for one minute, removed the strip, shook the strip once to remove excess fluid, and immediately read the test result. The technician failed to wait 20 seconds after removing the test strip to read the result.</p> <p>3. During an interview on 5/28/25 beginning at 4:37 AM, PCT 3 reported the total chlorine test strip could be read immediately after removing it from the sample.</p> <p>4. During an interview on 5/28/25 beginning at 10:14 AM, Charge Nurse 3 reported when performing a total chlorine test, staff should wait 20 seconds after removing the strip from the sample before reading the result.</p>			<p>immediately compare the strip color to the K100-0118F color chart to determine the Total Chlorine level in the sample. The color block that most closely resembles the color of the test strip is the total chlorine level of the sample.</p> <p>Effective 6/2/2025, the FA will conduct 3 days per week audits for 2 weeks utilizing the facility specific audit tool, with focus on ensuring the procedure for completing chlorine testing using the RPC strips are followed including but not limited to waiting 20 seconds for the test strip color to develop prior to comparing the strip color for results, 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 FA 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</p>

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V 0401 Bldg. 00	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT Based on observation, policy review, and interview, the dialysis facility failed to ensure staff transferred a patient with a Hoyer mechanical lift according to facility policy for 1 of 1 observation of a patient transfer using a Hoyer lift (Patient #13). Findings include:		V 0401	<p>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.</p> <p>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: 06/29/2025.</p>	06/29/2025

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	<p>1. The "Guidelines for Use of the Hoyer Lift" policy, dated 8/30/24, indicated when positioning the Hoyer lift to transfer a patient from a wheelchair to the treatment chair, staff should "not lock the brakes or block the wheels when lifting the patient. The wheels must be free to roll to allow the lift to center itself beneath the patient."</p> <p>2. During an observation on 5/28/25 beginning at 6:25 AM, PCT 3 and Charge Nurse 3 transferred Patient #13 from a wheelchair to the treatment chair using a mechanical Hoyer lift. The staff locked the wheels of the Hoyer when lifting Patient up from the wheelchair.</p> <p>3. During an interview on 5/28/25 beginning at 1:19 PM, PCT 3 reported the Hoyer lift wheels should be locked when lifting a patient up from a wheelchair.</p> <p>4. During an interview on 5/28/25 beginning at 1:54 PM, Charge Nurse 3 reported the Hoyer lift wheels should be locked when lifting a patient up from a wheelchair.</p>			<p>the wheels when lifting the patient. The wheels must be free to roll to allow the lift to center itself beneath the patient. Effective 6/2/2025 the FA will conduct 3 days per week audits, for 2 weeks, utilizing the facility specific audit tool with focus on ensuring the wheels on the hoyer lift are not locked or blocked with lifting the patient, 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. The FA 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. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight,</p>

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V 0407 Bldg. 00	<p>494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS</p> <p>Based on observation and interview, the dialysis facility failed to ensure all patient access sites were visible for 1 of 2 days of ICHD treatment floor observations (Patients #14, 15).</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. The policy "Patient Assessment and Monitoring," dated 5/01/23, indicated staff were to ensure the patient's access site "remains uncovered throughout the treatment." 2. During an ICHD treatment floor observation on 5/28/25 beginning at 4:50 AM, the following was observed: <ol style="list-style-type: none"> a. At 5:25 AM, Patient #15 was receiving dialysis 		V 0407	<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. 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. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 6/29/2025.</p> <p>On 5/30/2025, the FA held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policies.</p> <ul style="list-style-type: none"> · Initiation of Treatment Using a Central Venous Catheter (CVC) and Optiflux Single Use Ebeam Dialyzer Emphasis will be placed on: <ul style="list-style-type: none"> · Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. · Observe connections are secure and visible. o If an external catheter is in use, 	06/29/2025

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	<p>in Station 2. Patient's access site was not visible.</p> <p>At 5:40 AM, PCT 3 was in Station 2 at the dialysis machine. Patient's access was not visible. The technician failed to instruct Patient to keep their access visible.</p> <p>b. At 5:46 AM, Patient #14 was receiving dialysis in Station 1. Patient's access site was not visible.</p> <p>c. At 6:00 AM, RN 2 was in Station 2 obtaining performing safety checks. Patient #15's access site was not visible. The nurse failed to instruct Patient to keep their access site visible.</p> <p>d. At 6:04 AM, PCT 5 silenced alarms in Stations 1 and 2. Patients #14 and #15's access sites were not visible. The technician failed to instruct the patients to keep their access sites visible.</p> <p>e. At 6:33 AM, Charge Nurse 3 was in Station 1 performing safety checks. Patient #14's access site was not visible. The nurse failed to instruct Patient to keep their access site visible.</p> <p>3. During an interview on 5/28/25 beginning at 10:14 AM, Charge Nurse 3 reported staff should be monitoring patient access sites for visibility every 30 minutes, and staff also "keep an eye on" patients throughout their treatment. If an access site was covered, staff should "uncover it."</p> <p>4. During an interview on 5/28/25 beginning at 1:19 PM, PCT 3 reported staff should be monitoring patient access sites for visibility every 30 minutes and "whenever walking by" the patient.</p> <p>5. During an interview on 5/28/25 beginning at 1:47 PM, PCT 5 reported staff should be</p>			<p>observe and document that the HemaClip device is in place.</p> <ul style="list-style-type: none"> o Ensure access remains uncovered throughout the treatment o Observe and ensure: <ul style="list-style-type: none"> § Tape is secure § Needles are intact § No bleeding or infiltration is noted · Document any findings and interventions in the medical record. <p>Effective 6/2/2025, the FA will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring all patient accesses are uncovered and visible the entire treatment, and any abnormal findings are documented and reported to the RN. 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 FA 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</p>	

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

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	<p>monitoring patient access sites for visibility every 30 minutes. Staff also "glance" at the access sites while walking by. If a patient's access site was covered, staff should educate the patient and ask them to uncover the site.</p> <p>6. During an interview on 5/28/25 beginning at 1:58 PM, RN 2 reported staff should be monitoring patient access sites for visibility every 30 minutes. If access sites were not visible, staff should move blankets or other items to ensure the access was visible.</p>		<p>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.</p> <p>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: 6/29/2025</p>	