

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152537	(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	(X3) DATE SURVEY COMPLETED 06/12/2025
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CROWN POINT		STREET ADDRESS, CITY, STATE, ZIP COD 851 W BURRELL DR CROWN POINT, IN 46307		
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E 0000 Bldg. 00	<p>An Emergency Preparedness Survey was conducted by the Indiana State Department of Health in accordance with 42 CFR 494.62</p> <p>Survey Dates: 06/09/2025, 06/10/2025, 06/11/2025, 06/12/2025</p> <p>Facility Number: 005142 CCN: 152537</p> <p>Census: In Center Hemodialysis Patients: 68</p>	E 0000		
E 0023 Bldg. 00	<p>403.748(b)(5), 416.54(b)(4), 418.113(b)(Policies/Procedures for Medical Documentation</p> <p>Based on record review, observation, and interview, the dialysis facility failed to have a system of medical documentation that secures and maintains availability of patient records and staff information in an emergency/ evacuation.</p> <p>Findings include:</p> <p>A revised policy, dated 07/03/2023, titled "Guidelines for Emergency Preparedness", indicated that staff and patient emergency information contact lists should be updated quarterly and be kept locked in the emergency supply box.</p> <p>During an observation on 04/02/2025, beginning at 10:37 AM, a review of the dialysis facility emergency preparedness kit failed to evidence a current list of patients/ demographics/ dialysis prescription/ staff emergency contact information.</p>	E 0023	<p>By 7/8/25, the Clinical Manager will hold 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"> • Guidelines for Emergency Preparedness <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> • The Clinical Manager has a responsibility to maintain current listings of patients and staff including local contact; emergency contact and evacuation contact information. • Quarterly, the Clinical Manager will review and update per policy. <p>On 6/12/2025, the Clinical Manager placed the Emergency and Disaster Patient & Staff Contact Information Sheets in the Emergency Evacuation Box.</p>	07/11/2025

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

TITLE

(X6) DATE

Shauna Valdivia

Director of Operations

07/08/2025

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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	<p>An Emergency Disaster Patient Contact List, dated 03/27/2023 and an Emergency Disaster Staff Contact Information Sheet, dated 03/13/2023, was found in the emergency preparedness kit.</p> <p>During an interview, on 06/11/2025 beginning at 11:45 AM, the Facility Administrator [FA] indicated patient and staff emergency information was located in a binder in an office room and that staff would need to obtain this binder during an evacuation. The FA additionally indicated that the same information is located in the emergency preparedness kit.</p> <p>During an interview on 06/11/2025, beginning at 1:35 PM, RN 3 indicated that the staff would find patient and staff emergency information in the emergency preparedness kit in the event of an evacuation. Additionally, RN 3 relayed there was no other binder that she was aware of that would need to be obtained in the event of an evacuation.</p>		<p>Effective 07/09/2025, the Director of Operations will conduct monthly audit with focus on ensuring the Emergency Contact List for Patient's & Staff are quarterly updated, as required, utilizing specific plan of correction Audit Tool for 3 months and then an additional 3 months 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 Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the 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>	

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E 0039 Bldg. 00	<p>403.748(d)(2), 416.54(d)(2), 418.113(d)(2) EP Testing Requirements</p> <p>Based on record review and interview, the dialysis facility failed to evidence exercises were conducted to test the emergency plan, annually at minimum, in 1 of 1 dialysis facility.</p> <p>Findings include:</p> <p>A revised policy, dated 07/03/2023, titled "Guidelines for Emergency Preparedness", indicated that annually, the dialysis facility must participate in a community-based disaster drill as well as a table-top drill for an event of high likelihood.</p> <p>Clinic documents provided for review included a loss of water tabletop exercise including scenario and staff sign-in log dated 04/17/2025 and 04/18/2025. Additionally, a flooded roads tabletop exercise information and staff sign-in log dated 03/07/2024 was provided.</p> <p>During an interview on 06/11/2025, beginning at</p>	E 0039	<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>By 7/8/2025, the Clinical Manager will hold 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"> • Guidelines for Emergency Preparedness <p>Emphasis will be placed on:</p> <ul style="list-style-type: none"> • Annually, each facility must participate in a community-based disaster drill. If unable to participate, document who you contacted in the community and why the clinic was unable to participate on the Facility Specific Disaster Safety Plan form. If the EOC or similar agency has not performed a community-based drill, or it was missed for a particular year, the DO should coordinate a dialysis facility area-based drill. • The Governing Body will: 	07/11/2025

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	2:55 PM, the Facility Administrator [FA] indicated that these two trainings were the only training exercises completed in the last two years. The FA indicated that no community-based or full-scale exercise has been completed since approximately 2020, and no real-world events that would cause the facility to activate the emergency preparedness plan had occurred in the last two years.			<ul style="list-style-type: none"> Review and approve the Facility Specific Disaster Safety plan initially and annually. <p>On 04/17/2025, the Clinical Manager conducted a facility Table-Top Drill on "Water Interruption", with an completed after-action review with all staff. Materials with signature page are located at facility and available for review upon request.</p> <p>On 05/15/2025 & 05/16/2025, the facility had an actual event with "Power Loss/High Winds" and conducted an after-action review on 07/07/2025 with all staff. Details surrounding this event with the signature page will be located at the facility and available for review upon request.</p> <p>The updated Facility Specific Disaster Safety Plan will be reviewed at the facility's next Governing Body meeting, scheduled for 07/16/2025. The minutes of this meeting will be located at the facility and available for review upon request.</p> <p>Effective 07/09/2025, the Director of Operations will conduct monthly audits utilizing a specific plan of correction audit tool for 3 months, and then an additional 3 months or until 100% compliance is achieved. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAPI calendar. Monitoring will be</p>	

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			<p>done through the specific plan of correction audit tool.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the 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>	

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V 0000 Bldg. 00	<p>This visit was for a CORE Federal recertification survey of an ESRD provider.</p> <p>Survey dates: 06/09/2025 - 06/12/2025</p> <p>Census by Service Type:</p> <p>In-Center Hemodialysis: Home Hemodialysis: 68</p> <p>Isolation Room: 0, isolation provided by agreement with another ESRD.</p> <p>The abbreviations used in this survey include: FA for facility administrator, RN for registered nurse, PCT for Patient Care Technician.</p> <p>A 1, 6/25/2025</p>	V 0000		
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 staff performed hand hygiene and changed their gloves in 1 of 3 observations of accessing of an arteriovenous fistula [AVF] (dialysis access) for initiation of dialysis [PCT 5] and in 1 of 4 observations of discontinuation and post dialysis access care for AVF [PCT4].</p> <p>Findings include:</p> <p>1. A revised policy, dated 11/06/2023, titled "Hand Hygiene", indicated that hand hygiene should be performed before and after direct contact with</p>	V 0113	<p>By 7/8/2025, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure:</p> <ul style="list-style-type: none"> · Hand Hygiene <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> · Hands will be decontaminated using alcohol-based hand rub (without waving hands to dry, due to potential air borne contaminants) or by washing hands with antimicrobial soap and water: o Before and after direct contact 	07/11/2025

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	<p>patients, before performing vascular access, and after contact with dialysis equipment.</p> <p>2. During an observation on 06/09/2025, beginning at 11:29 AM, PCT 5, at station # 17, was accessing an AVF for initiation of dialysis and palpated the AVF cannulation sites of Patient 7. PCT 5 failed to perform hand hygiene and don new gloves prior to disinfecting the cannulation site and inserting the needles.</p> <p>3. During an observation on 06/09/2025, beginning at 10:45 AM, PCT 4, at station #10, was discontinuing hemodialysis [HD] (a process to filter the blood in a patient whose kidneys do not work normally) for Patient 9. PCT 4 reinfused the HD machine and failed to perform hand hygiene and don new gloves prior to removing the needles from Patient 9.</p> <p>4. During an interview, on 06/11/2025 beginning at 11:56 AM, PCT 4 indicated that hand hygiene should be performed frequently before contact with the patient and equipment.</p>		<p>with patients</p> <ul style="list-style-type: none"> o Entering and leaving the treatment area o Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications 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 o After contact with the dialysis wall box, concentrate, drain, or water lines. o After contact with other objects within the patient station or treatment space <ul style="list-style-type: none"> · Washing Hands with Soap and Water - Duration of the entire procedure: 40-60 seconds · Decontaminating Hands with Alcohol Based Hand rubs - Duration of the entire procedure: 20-30 seconds. o Apply alcohol-based hand rub to the palm of one hand using the amount recommended by the product manufacturer. An adequate amount of product must be used for maximum effectiveness. 	

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			<ul style="list-style-type: none"> o Rub hands together covering all surfaces of the hands and fingers, until hands are dry. Allowing alcohol to dry completely allows adequate contact time to kill germs, allows alcohol to evaporate and prevents risk of igniting flames due to alcohol's flammable. Effective 7/9/2025, the Clinical Manager or Charge Nurse will conduct infection control audits weekly, 3 times per week, with alternating shifts with focus on ensuring staff perform hand hygiene per policy, as required, utilizing Infection Control Monitoring Tool for 2 weeks and then 2 times per week for an additional 2 weeks or until 100% 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 QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the 	

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V 0143 Bldg. 00	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS Based on observation, record review, and interview, the dialysis facility failed to ensure RN 1 demonstrated aseptic techniques when administering parenteral medications in 2 of 2 observations of parenteral medication preparation and administration. Findings include: 1. A revised policy, dated 02/06/2025, titled, "Medication Preparation and Administration" indicated aseptic technique was to be used to		V 0143	<p>resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking 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 QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>	07/11/2025

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	<p>administer medications and IV ports should be disinfected prior to accessing.</p> <p>2. During an observation, on 06/10/2025 beginning at 1:09 PM, RN 1 failed to disinfect the injection port prior to administering parenteral medication to Patient 18.</p> <p>3. During an observation, on 06/10/2025 beginning at 1:16 PM, RN 1 failed to disinfect the injection port prior to administering parenteral medication to Patient 3.</p> <p>4. During an interview, on 06/11/2025 beginning at 1:35 PM, RN 3 indicated that the injection port should be cleaned and disinfected prior to administering parenteral medication.</p>		<p>administering medications</p> <ul style="list-style-type: none"> · Aseptic technique will be used to prepare and administer IV medications. Medications shall be prepared in a clean work area away from dialysis patient stations and delivered separately to each patient. · Common medication carts and trays shall not be used to deliver medications from patient station to patient station. · Disinfect IV ports prior to accessing, using friction and 70% alcohol, iodophor or chlorhexidine/alcohol agent. Cleanse the diaphragm with a new alcohol wipe each time an IV port is accessed. Allow to dry prior to accessing. · Never use medication in a syringe for more than one patient even if the needle is changed between patients. · Always use a sterile syringe and needle when entering a vial. o If both vials are single use and are discarded after the single entry into each, the same syringe may be used. If either vial is multi-use a different syringe must be used for entry into each vial. · Cleanse the diaphragm of a vial with alcohol prior to accessing the vial. If the vial is a multidose vial, cleanse the diaphragm with a new alcohol pad each time the vial is accessed with a needle using friction and 70% alcohol. Allow to dry before inserting a device into 	

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				<p>the vial.</p> <ul style="list-style-type: none"> Discard single-dose vials after use. Never reuse for another patient. For single dose vials, never puncture the vial twice. Never store vials in clothing or pockets. Never pool or combine leftover contents of vials for later use. Never leave a needle inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination. Examine the vial for any particulate matter, discoloration, or turbidity. If present, do not use and discard immediately. <p>Effective 7/09/2025, the Clinical Manager or Charge Nurse will conduct infection control audits weekly, 3 times per week, with alternating shifts with focus on ensuring staff disinfect IV ports prior to accessing for medication administration per policy, as required, utilizing Infection Control Monitoring Tool for 2 weeks and then 2 times per week for an additional 2 weeks or until 100% 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 QAI Committee meeting monthly.</p>	

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V 0190 Bldg. 00	494.40(a) SOFTENERS-AUTO REGENERATE/TIMERS/SALT LVL Based on observation and interview, the facility failed to ensure the softener brine tank was at least half filled with salt pellets in 1 of 1	V 0190	<p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</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 QAI Committee is responsible for providing oversight, reviewing findings, and taking 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 QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>	07/11/2025

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	<p>observation of the water room.</p> <p>The findings include:</p> <p>During an observation on 06/10/2025, beginning at 11:26 AM, the softener brine tank failed to contain salt pellets.</p> <p>On 06/10/2025, at 11:33 AM, Corporate Person 2 indicated there was not any salt pellets in the softener brine tank, because the facility had run out of salt pellets and the delivery truck had just arrived with more.</p>		<p>responsibilities of the facility staff on policy and procedure:</p> <ul style="list-style-type: none"> · Water Softener Policy <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> · Salt levels inside brine tanks will be maintained at a minimum of half full. <p>Effective 7/09/2025, the Clinical Manager or Charge Nurse will conduct audits weekly, 3 times per week, with alternating shifts with focus on ensuring salt levels inside brine tank are maintain and at a minimum half full with salt at all times per policy, as required, utilizing Plan of Correction Audit Tool for 2 weeks and then 2 times per week for an additional 2 weeks or until 100% 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 QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</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</p>	

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V 0199 Bldg. 00	<p>494.40(a)</p> <p>RO-MEETS AAMI/MONITORED, RECORDED ON LOG</p> <p>Based on observation, record review, and interview, the facility failed to ensure all the results of the measurements of the reverse osmosis (RO) performance were documented correctly in 1 of 1 observation of the water room.</p> <p>The findings include:</p> <p>During an observation on 06/10/2025, beginning at 11:26 AM, the softener brine tank failed to contain salt pellets.</p> <p>On 06/10/2025, at 11:33 AM, Corporate Person 2 indicated the agency ran out of salt pellets the</p>	V 0199	<p>each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking 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 QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>	07/11/2025

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	<p>day prior.</p> <p>The Water Pre-Treatment Opening document completed by PCT 4 indicated the softener brine tank was at least half full on 06/10/2025.</p> <p>On 06/10/2025, the BioMed Technician indicated PCT 4 notified him the day before on 06/09/2025 that the salt pellet level was low in the softener brine tank and indicated PCT 4 should not have documented the salt pellet level was at least half full in the softener brine tank on 06/10/2025.</p> <p>On 06/11/2025, at 11:55 AM, PCT 4 indicated there were no salt pellets in the softener brine tank but marked the level was at least half full, because he knew the shipment of salt pellets would be delivered that day.</p>		<p>sure the tank is at least half filled with salt, adding salt pellets if necessary.</p> <ul style="list-style-type: none"> o Control head time clock / pre-treatment controller times are set correctly. o Pre and post water softener pressures. o Calculate Delta Pressure – Per manufacturer's IFU or obtained by the manufacturer at the time of installation. o Hardness levels post water softener (if installed) at the beginning of each operational day and at the end of each operational day. · Staff will notify Clinical Manager immediately if no salt available at facility to add to brine tank. <p>Effective 7/09/2025, the Clinical Manager or Charge Nurse will conduct audits weekly, 3 times per week, with alternating shifts with focus on ensuring salt levels inside brine tank are maintain and at a minimum half full with salt for RO to function properly at all times per policy, as required, utilizing Plan of Correction Audit Tool for 2 weeks and then 2 times per week for an additional 2 weeks or until 100% 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</p>	

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V 0407	494.60(c)(4) PE-HD PTS IN VIEW DURING			<p>the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</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 QAI Committee is responsible for providing oversight, reviewing findings, and taking 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 QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>

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Bldg. 00	<p>TREATMENTS</p> <p>Based on observation, record review, and interview, the facility failed to ensure the patient's hemodialysis (HD, a process to filter the blood in a patient whose kidneys do not work normally) access site was in view while receiving HD treatment in 1 of 2 treatment floor observations. (Patient #14)</p> <p>The findings include:</p> <p>A policy titled "Patient Assessment and Monitoring" dated 05/01/2023 indicated the access site was to remain uncovered during the treatment.</p> <p>During an observation on 06/09/2025, from 10:30 AM to 11:32 AM, Patient #14 had multiple blankets covering the central venous catheter (CVC, dialysis access) while treatment was provided.</p> <p>During an interview on 06/09/2025, at 11:55 AM, Patient #14 indicated they were unaware the access site had to be visible and uncovered during the treatment.</p> <p>On 06/12/2025, at 11:55 AM, the FA indicated staff should have removed the blankets covering the Patient's access site.</p>	V 0407	<p>By 7/8/2025, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure:</p> <ul style="list-style-type: none"> · Patient Assessment and Monitoring <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> · Ensure access remains uncovered throughout the treatment <p>Effective 7/09/2025, the Clinical Manager or Charge Nurse will conduct audits weekly, 3 times per week, with alternating shifts with focus on ensuring patient's access remains uncovered throughout the treatment per policy, as required, utilizing Infection Control Audit Tool for 2 weeks and then 2 times per week for an additional 2 weeks or until 100% 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 QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p>	07/11/2025

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V 0470 Bldg. 00	494.70(c) PR-RIGHTS POSTED, STATE/NW ONTACT INFO Based on observation and interview, the dialysis facility failed to ensure Patients' Rights were posted where it could be easily seen and read by all patients in 1 of 1 facility. Findings include:	V 0470	<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 QAI Committee is responsible for providing oversight, reviewing findings, and taking 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 QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>	07/11/2025

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	<p>During an observation upon entrance to the dialysis facility on 06/09/2025, beginning at 10:25 AM, the lobby failed to evidence posting of Patient's Rights.</p> <p>During an interview on 06/09/2025, beginning at 4:40 PM, the Facility Administrator indicated that the Patient Rights should be posted in the lobby and will need to determine why they are not posted.</p>		<ul style="list-style-type: none"> · All facilities should post the Patient and Staff Partnership Poster where it is easily visible and accessible to patients. Copies of the FMCNA Rights and Responsibilities brochures should be placed in the designated pockets on the poster. Multiple quantities of these brochures should be available at all times. Effective 7/09/2025, the Clinical Manager will conduct audits weekly, 3 times per week, with alternating shifts with focus on ensuring patient's rights and responsibilities poster is available in the patient lobby for all patients to view per policy, as required, utilizing Infection Control Audit Tool for 2 weeks and then 2 times per week for an additional 2 weeks or until 100% 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 QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status 	

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V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P Based on observation, record review, and interview, the dialysis facility failed to ensure that policies and procedures relative to patient care, infection control, and safety were adhered to by the dialysis facility staff in 3 of 3 personnel records reviewed [PCT 4, PCT 5, and RN1], in 1 of 3 [PCT 5] observations of accessing an arteriovenous fistula [AVF] (dialysis access) or arteriovenous graft [AVG] (dialysis access) for initiation of hemodialysis [HD] (a process to filter		V 0715	<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 QAI Committee is responsible for providing oversight, reviewing findings, and taking 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 QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>	07/11/2025

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	<p>the blood of a patient whose kidneys do not work normally), 1 of 4 observations [Patient 16] of HD treatment prescription delivery verification, and 1 of 1 clinical record review of an unstable patient [Patient 3].</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. A revised policy, dated 01/23/2019, titled "Color Blindness Testing", indicated that the staff member being tested record test answers on the answer sheet and the direct supervisor should score the test overall as "pass" or "fail". Additionally, the policy indicated that 10 or more answers correct on questions 1-11 would indicate a "pass" result, and 9 or less correct answers would indicate a "fail" result. Answers to questions 12-14 will not be factored into the final test score. 2. A revised policy, dated 05/05/2025, titled "Access Assessment and Cannulation", indicated that prior to cannulating, an AVF or AVG should be checked for adequate bruit (sound generated by the flow of blood) to confirm patency by listening for abnormal or absent sounds by auscultation with a stethoscope. 3. A revised policy, dated 05/01/2023, titled "Patient Assessment and Monitoring", indicated that required patient monitoring included checking that the dialysate flow rate [DFR] setting is correct, and that the prescribed flow rate is being delivered. 4. During a review of personnel records provided by the dialysis facility on 06/10/2025, the following observations were made regarding the color-blind testing results: 		<p>Use the Ishihara Test Chart Book for Color Blindness (14 plates)</p> <ol style="list-style-type: none"> 1. Ask person to identify the numbers seen in each plate and record on the answer sheet. Do not prompt the person in any way. 2. Review complete results and score the overall test as "pass" or "fail". 3. Maintain documentation of test results in the employees medical file. 4. A passing score on the Ishihara Test is defined as follows: <ul style="list-style-type: none"> · If 10 or more of plates 1 through 11 are read correctly, the color vision is normal, and the test is read as "pass". · If 7 or fewer of plates 1 through 11 are read correctly, the color vision is deficient, and the test is read as "fail". · If the person receives a score of 8 or 9, the assessment is inconclusive and should be interpreted as "fail". · o Plates 12 through 14 specifically test for red-green deficiencies. The results of those plates are not factored into the final test score. · Record results of the color blindness screening as 'pass' or 'fail' on the Color and Quality Test Screen Results Form. <p>Follow the steps below to assess the vascular access:</p> <ol style="list-style-type: none"> 1. Prior to treatment, ask patient to wash access area with soap and water, per hand hygiene 	

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	<p>A. A Color and Quality Test Screen Results form, dated 06/03/2025, for RN 1, failed to evidence a score, nor a "pass" result, nor a "fail" result.</p> <p>B. A Color and Quality Test Screen Results form, dated 08/22/2024, for PCT 5, did not contain a score, nor a "pass" result, nor a "fail" result. The form indicated a "pass" result in the "home therapy use only" section. The form additionally indicated that questions 12-14 were answered correctly, but no score was noted for questions 1-11.</p> <p>C. A Color Deficiency Test form, dated 09/30/2016, for PCT 4, did not contain a score, nor a "pass" result, nor a "fail" result in the designated results section.</p> <p>D. During an interview, on 06/10/2025 beginning at 2:45 PM, the Facility Administrator [FA] indicated that all the color-blind tests had been passed by staff, even if it had not been marked so on the test forms. The FA agreed that based on the documentation given to the surveyor, clear results could not be interpreted.</p> <p>5. During an observation, on 06/09/2025 beginning at 11:29 AM, PCT 5 was at station # 17, performing access of an AVF to Patient 7. PCT 5 located and palpated the cannulation site and failed to auscultate bruit of the AVF prior to cannulation of the AVF site.</p> <p>During an interview, on 06/11/2025 beginning at 11:56 AM, PCT 4 indicated that the bruit of an AVF or AVG should be auscultated prior to AVF/AVG cannulation.</p> <p>6. During an observation, on 06/10/2025 beginning at 1:27 PM, Patient 16 was at station #8, had a</p>		<p>procedure. If the patient is unable to wash their own access, the staff or care partner should wear gloves to wash the patient's access with soap and water.</p> <p>2. Wash hands and don PPE: gloves, gown/apron, safety glasses and mask, or full-face shield.</p> <ul style="list-style-type: none"> o If patient is performing self-cannulation, he/she should don gloves. If using buttonhole technique, apply gloves and mask. <p>3. Place underpad under access to prevent soiling surrounding area.</p> <p>4. ASK: complaints of pain, numbness, tingling, coldness and tenderness, fever.</p> <ul style="list-style-type: none"> o Document in treatment record. <p>5. LOOK:</p> <ul style="list-style-type: none"> o Skin <ul style="list-style-type: none"> Discoloration/Redness/Bruising/Lesion o Hematomas o Extremity or Other Swelling o New or change in aneurysm or pseudoaneurysm o Poor rotation of cannulation sites o Pus o Greater than Expected Redness o Greater than Expected Swelling o Any other unusual findings o Document in treatment record. <p>6. LISTEN: o Bruit high pitch/whistle</p> <ul style="list-style-type: none"> o Bruit not present throughout access Document in treatment record. Clean stethoscope after assessing a patient. · If direction of flow is not documented in the patient's medical record, compress in the 	

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	<p>DFR running on "autoflow" (a feature that varies DFR rate based on blood flow) during treatment; the prescribed DFR was 800.</p> <p>A Treatment Sheet, dated 06/10/2025, for Patient 16, the DFR had been set to the rate of "autoflow" from the start of treatment at 11:09 AM until 1:35 PM.</p> <p>During an interview, on 06/10/2025 beginning at 1:27 PM, RN 1 indicated that the prescription for DFR was 800, and that the running DFR should have been 800.</p> <p>7. A clinical record review on 06/12/2025, for Patient 3, indicated the following:</p> <p>A. A Treatment Sheet, dated 05/22/2025, indicated the DFR was run at 500 for the entire treatment, and that the prescribed DFR was 800.</p> <p>B. A Treatment Sheet, dated 06/07/2025, indicated the DFR was run at 500 for the entire treatment, and that the prescribed DFR was 800.</p> <p>During an interview on 06/11/2025, beginning at 1:35 PM, RN 3 indicated that DFR's should be run at the rate the dialysis prescription specifies and that if a different rate needs to be run, the MD would need to place a new order.</p> <p>8. A clinical record review for Patient #6 evidenced an order dated 04/30/2025 which indicated the BFR was 350. The Treatment Sheet for 05/26/2025 indicated the BFR was 375 and the Treatment Sheets for 05/14/2025, 05/16/2025, 05/26/2025, and 05/30/2025 indicated the BFR was 400.</p> <p>9. During an interview on 06/11/2025, beginning at 1:35 PM, RN 3 indicated that DFR's should be run</p>		<p>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. · If no sounds present, assume the access is thrombosed and do not attempt cannulation. The Nurse will communicate with the physician for referral to the interventionalist/surgeon.</p> <p>7. FEEL: o Pulse not soft/not easily compressible o Thrill not strong at anastomosis o Thrill not present throughout access · Document in treatment record.</p> <p>8. Note and report any unusual findings to the nurse in charge or home therapies staff before proceeding with needle insertion.</p> <p>9. Remove gloves and perform hand hygiene. Don new gloves. · Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations.</p> <p>o Check machine settings and measurements:</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>§ Check dialysate flow rate setting is correct, and the prescribed flow is being delivered.</p> <p>On 6/11/2025, the Clinical</p>	

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

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	at the rate the dialysis prescription specifies and that if a different rate needs to be run, the MD would need to place a new order.		<p>Manager reviewed 100 % of all current clinical staff for the Color blindness test. Any outliers not administered & document correctly per policy for Color Blindness test, Manager will immediately administer.</p> <p>Effective 7/09/2025, the Clinical Manager will conduct audits weekly, 3 times per week, with alternating shifts with focus on ensuring all staff have Color Blindness Test administered/document; staff performing cannulation on patient's accesses to listen to access prior to cannulation; per policy, as required, utilizing Personnel Tracker Audit Tool; Infection Control Audit Tool; and Treatment Sheet Audit Tool for 2 weeks and then 2 times per week for an additional 2 weeks or until 100% 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>Effective 7/09/2025, Clinical Manager or Charge Nurse will conduct 10 treatment sheets daily, 3 times per week alternating shifts, with focus on ensuring patient dialysis prescription orders are verified and adhered to in order to achieve and sustain the prescribed dose of dialysis to meet the adequacy of dialysis</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152537	(X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	(X3) DATE SURVEY COMPLETED 06/12/2025
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE CROWN POINT		STREET ADDRESS, CITY, STATE, ZIP COD 851 W BURRELL DR CROWN POINT, IN 46307		
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			<p>utilizing Treatment Sheet Audit Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks or until 100% 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 QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</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 QAI Committee is responsible for providing oversight, reviewing findings, and taking 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 QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure</p>	

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V 0726 Bldg. 00	<p>494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE</p> <p>Based on observation, record review, and interview, the facility failed to ensure medical records were accurate in 1 of 1 clinical record review of a patient who did not have the access site in view while receiving hemodialysis (HD, a process to filter the blood in a patient whose kidneys do not work normally) during observation of the HD treatment floor. (Patient #14)</p> <p>The findings include:</p> <p>During an observation on 06/09/2025, from 10:30 AM to 11:32 AM, Patient #14 had multiple blankets covering the central venous catheter (CVC, dialysis access) while treatment was provided.</p> <p>A Treatment Sheet for Patient #14 dated 06/09/2025 indicated the dialysis access site was visible at 10:33 AM and 11:04 AM.</p> <p>On 06/12/2025, at 11:55 AM, the FA indicated the staff should have documented the access site was covered by the blankets, and the Patient was re-educated on leaving the access site visible.</p>		V 0726	<p>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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>By 7/8/2025, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure:</p> <ul style="list-style-type: none"> · Patient Assessment and Monitoring <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> · Ensure access remains uncovered throughout the treatment <p>Effective 7/09/2025, the Clinical Manager or Charge Nurse will conduct audits weekly, 3 times per week, with alternating shifts with focus on ensuring patient's access remains uncovered throughout the treatment per policy, as required, utilizing Infection Control Audit Tool for 2 weeks and then 2 times per week for an additional 2 weeks or until 100% is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done</p>	07/11/2025

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			<p>through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</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 QAI Committee is responsible for providing oversight, reviewing findings, and taking 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 QAI monthly.</p> <p>The Governing Body is responsible for providing 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 QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>	