

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

PRINTED: 10/20/2023
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152520	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 08/29/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA			STREET ADDRESS, CITY, STATE, ZIP CODE 710 PARK PL MISHAWAKA, IN 46545		
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E 000	Initial Comments An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62. Survey Dates: 8/22/2023, 8/23/2023, 8/24/2023, 8/25/2023, 8/28/2023, 8/29/2023 Census: 87 At this Emergency Preparedness survey, Fresenius Medical Care Mishawaka, was found to have been in compliance with the Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers, including staffing and the implementation of staffing during a pandemic at 42 CFR 494.62.	E 000			
V 000	INITIAL COMMENTS This visit was a CORE Federal recertification survey of an ESRD provider which resulted in an Immediate Jeopardy. Survey dates: 8/22/2023, 8/23/2023, 8/24/2023, 8/25/2023, 8/28/2023, 8/29/2023 Census by Service Type: In-Center Hemodialysis: 87 Total Census: 87 Isolation Room/Waiver: yes Fresenius Medical Care- Mishawaka was found to be out of compliance with Conditions of Participation 42CFR 494.80 Patient Assessment,	V 000			

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

TITLE

(X6) DATE

09/28/2023

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V 000	Continued From page 1 and 42CFR 494.30 Plan of Care	V 000			
V 110	<p>Immediate Jeopardy related to 42 CFR 494.80, Patient Assessment, began on 6/19/2023, when the review of the patient records identified, the provider had failed to implement their policy when they failed to notify the physician of the patient beginning below his dry weight and having nausea and vomiting. The Facility Administrator was notified of the immediate jeopardy on 8/28/2023 at 4:40 PM. The immediate jeopardy was not removed prior to exit on 8/29/2023.</p> <p>CFC-INFECTION CONTROL CFR(s): 494.30</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview the dialysis center failed to ensure staff maintained a sanitary environment (V111), failed to performed proper hand hygiene (V113), failed to use proper protective equipment (V115), failed to ensure items taken to the dialysis station were disinfected (V116) failed to ensure dialysis stations were disinfected appropriately (V122), failed to ensure the staff practiced, infection control standards in the administration of medication using of muti-dose medication vials (V143) and failed to ensure catheter hubs were disinfected (V147).</p> <p>The cumulative effect of these systemic problems has resulted in the dialysis center's inability to ensure provision of quality health care in a safe environment for the condition of participation 42CFC 494.30. Infection Control.</p>	V 110			

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V 111	<p>IC-SANITARY ENVIRONMENT CFR(s): 494.30</p> <p>The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the dialysis facility failed to ensure it provided and monitored a sanitary environment.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. An agency policy titled "General Cleanliness and Infection Control Guidelines," published 2/7/2022, stated, " ... All treatment areas must be kept clean and organized, including but not limited to the treatment area, water supply room, and offices. Walkways must be clear of debris and free of clutter...." 2. Observation of the treatment area on 8/22/2023 at 9:35 AM revealed a countertop near station 1, with designated areas marked "clean" and "dirty". Two containers of bleach solution failed to evidence the date/time the solutions were mixed. 3. Observation of the treatment area on 8/22/2023 at 11:00 AM revealed a ledge above a sink marked "dirty" (near station 10). On the ledge, sat an uncovered container of bleach solution which contained cloths used for disinfecting equipment, and an uncovered clean container of hemostats (clamps), with its lid located under the container. 	V 111			

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V 111	<p>Continued From page 3</p> <p>4. Observation of the treatment area on 8/22/2023 at 11:13 AM revealed standing water on the floor under a sink marked "dirty", near station 7.</p> <p>5. Observation of the treatment area on 8/22/2023 at 11:24 AM revealed a used glove sitting on the edge of a sink marked "clean", and was hanging down into a trash can, which was nearly full of garbage.</p> <p>6. Review of a facility document with date range 9/01/2022 - 8/22/2023, titled "Clinic Audit Checklist", evidenced the document was a log to record completion of monthly infection prevention audits. The subtitle was "Category: Infection Prevention", with 2 audit topics. Monthly audits for cleaning and disinfection of the dialysis station were conducted 5 out of 12 months listed on the log, and monthly audits for isolation practices were conducted 4 out of 12 months listed on the log.</p> <p>During an interview on 8/23/2023 at 3:38 PM, the Facility Administrator indicated she was behind on completing the audits in the computer, but she had a lot of paper notes she needed to get to.</p> <p>7. During the flash tour on 8/22/2023 at 9:40 AM, white pieces of paper, and a water test strip were observed on the floor by station 19.</p> <p>8. During the flash tour on 8/22/2023 at 9:41 AM, loose gloves were observed on the counter behind station 21.</p> <p>9. During the flash tour on 8/22/2023 at 9:42 AM, the trash can was full of trash can was overflowing and spilling trash onto the floor at</p>	V 111			

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V 111	<p>Continued From page 4</p> <p>station 22, failing to maintain a clean and sanitary environment.</p> <p>10. During the flash tour on 8/22/2023 at 9:43 AM, a blue chuck (absorbent pad) and a glove were on the floor by the desk across from stations 14/15.</p> <p>11. During the flash tour on 8/22/2023 at 9:45 AM, two used water test strips and a cup of clear liquid were on the shelf behind station 23.</p> <p>12. During an observation on 8/23/2023 at 11:01 AM, PCT 6 was observed initiating dialysis for patient #8 at station 22. PCT 6 opened packages and put contents on the chair side table, looked for the trash can, and proceeded to put the empty wrappers on the shelf behind the station. When performing exit site care. PCT 6 dropped used supplies onto the floor failing to maintain a clean environment.</p> <p>During an interview on 8/23/2023 at 11:26 AM, PCT 6 asked RN 2 where should she have put her trash while initiating dialysis for Patient #8. She then stated, "I just put it on the floor and picked it up when I was one, I cannot leave it with the clean stuff."</p> <p>During an interview on 8/23/2023 at 2:44 PM, the Facility Administrator (FA) indicated staff should keep the treatment area free of clutter so they can focus on patient care.</p> <p>During an interview on 8/23/2023 at 3:02 PM, the FA indicated they wanted to reduce the number of trash cans to make less trip hazards. We are just trying to clean up and make the environment better.</p>	V 111			

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V 113	<p>IC-WEAR GLOVES/HAND HYGIENE CFR(s): 494.30(a)(1)</p> <p>Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the dialysis facility failed to ensure all staff wore gloves during patient care, or when the patient's equipment was touched at the dialysis station; and failed to ensure all staff demonstrated proper hand hygiene procedures.</p> <p>The findings include:</p> <p>1. An agency policy titled "Hand Hygiene," published 3/17/2023 stated "Hand hygiene includes either washing hands with soap and water or using a waterless alcohol-based antiseptic rub with 60-90% alcohol content. Hands will be washed with antimicrobial soap and water when hands are visibly dirty or contaminated with proteinaceous material, blood, or other bodily fluids ... decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water before and after direct contact with patients. Entering and leaving the treatment area. Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications. Immediately after removing gloves. After contact with bodily fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled. When moving from a contaminated body site to a clean</p>	V 113			

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V 113	<p>Continued From page 6</p> <p>body site of the same patient. After contact with the dialysis wall box, concentrate, drain, or water lines"</p> <p>2. An agency procedure titled "Hand Hygiene," revised 9/26/2018 stated, "Procedure for Washing Hands with Soap and Water: 1. If gloves are worn remove and discard in appropriate waste container ... 2. Turn on warm running water ... 3. Wet hands with running water. Water is needed to lather soap. 4. Apply soap to hands using the amount recommended by the product manufacturer ... 5. Rub hands together vigorously. Cover all surfaces of the hands and fingers ... Duration of the entire procedure 40-60 seconds. 6. Rinse hands with running water and dry thoroughly with a disposable towel ... Turn of water faucet by using a hands free control or by touching the sink with wrist blades with a clean single use paper towel ... Procedure for Decontaminating Hands with Alcohol Based Hand rubs 1. If gloves are worn, remove and discard in appropriate waste container. Exposes the skin for decontamination. 2. Apply an alcohol-based hand rub to the palm of one hand using the amount recommended by the product manufacturer. Adequate amount of product must be used for maximum effectiveness. 3. 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 properties. Duration of the entire procedure: 20 to 30 seconds...."</p> <p>During an observation on 8/22/2023 at 11:06 AM, Patient Care Technician (PCT) 4 performed hand hygiene with hand sanitizer, and after rubbing her</p>	V 113			

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V 113	<p>Continued From page 7</p> <p>hands together, while still wet, she waved her hands to expedite the drying process.</p> <p>3. During an observation on 8/22/2023 at 11:09 AM, PCT 4 performed hand hygiene with hand sanitizer, and after rubbing her hands together, while still wet, she waved her hands to expedite the drying process.</p> <p>4. During an observation on 8/23/2023 at 10:51 AM, PCT 5 performed hand hygiene with hand sanitizer, and after rubbing her hands together, while still wet, she waved her hands to expedite the drying process.</p> <p>5. During an observation on 8/23/2023 at 2:15 PM, observed PCT 5 wore a glove to touch the dialysis machine computer screen, while the other hand remained ungloved. Observed this process repeated for care provided to patients at station 10, and again at station 11 (hand hygiene was performed in between each station). At 2:19 PM, after performing hand hygiene, PCT 5 gloved only the left hand, then placed her right hand behind her back, and touched the dialysis machine computer screen at station 13.</p> <p>During an interview on 8/23/2023 at 2:25 PM, PCT 5 indicated she wore only one glove because her hands were sweaty.</p> <p>6. During an observation on 8/24/2023 at 12:05 PM, PCT 4 performed hand hygiene with hand sanitizer, and after rubbing her hands together, while still wet, she waved her hands to expedite the drying process.</p> <p>7. During an interview on 8/23/2023 at 3:38 PM, the Facility Administrator (FA) indicated that after</p>	V 113			

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V 113	<p>Continued From page 8</p> <p>the removal of gloves, hand hygiene should occur, it should take at least 60-90 seconds for hand washing with soap and water, and if hand sanitizer was used, hands should be rubbed with friction until dry. The FA also indicated hand hygiene should occur before any patient contact, touching of machines, for cannulation, really all the time, and also between procedures; and staff should never wear only 1 glove, or wrap a glove around a finger to reset an alarm.</p> <p>8. During an observation on 8/22/2023 at 11:05 AM, PCT 3 was observed washing his hands with soap and water. PCT 3 completed the entire hand-washing procedure including drying his hands in 10 seconds.</p> <p>9. During an observation on 8/22/2023 at 11:17 AM, PCT 3 was observed washing his hands with soap and water. PCT 3 completed the entire hand-washing procedure including drying his hands in 12 seconds.</p> <p>10. During an observation on 8/22/2023 at 11:21 AM, PCT 5 was observed washing his hands with soap and water. PCT scrubbed with soap for 7 seconds and completed the entire hand-washing procedure including drying his hands in 17 seconds.</p> <p>11. During an observation on 8/22/2023 at 11:25 AM, PCT 5 was observed sanitizing her hands after rubbing the sanitizer on her hands, PCT 5 was waving her hands to dry them. PCT 5 failed to rub the sanitizer until dry.</p> <p>12. During an observation on 8/22/2023 at 11:27 AM, PCT 5 was observed cleaning the machine at station 17. PCT 5 removed her gloves</p>	V 113			

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V 113	<p>Continued From page 9</p> <p>sanitized her hands and was observed waving her hands to dry them. PCT 5 then was observed resetting an alarm on the machine at station 15. PCT 5 retrieved a glove from the box, wrapped it around her index finger, and reset the machine PCT 5 failed to don gloves prior to touching the machine.</p> <p>13. During an observation on 8/23/2023 at 11:19 AM RN 2 was observed reinfusing Patient #20 at station 18. RN 2 removed her gloves failed to hand hygiene, removed a key from her pocket, removed heparin from the central drawer, put the key back in her pocket, retrieved a new syringe from clean supplies and donned new gloves without performing hand hygiene.</p> <p>14. During an observation on 8/23/2023 at 1:50 PM, PCT 2 was observed at station 7 typing on the computer PCT 2 then cleansed patient 33's fistula site failing to perform hand hygiene and glove change prior to cleaning the Patient's fistula.</p> <p>15. During an observation on 8/23/2023 at 2:00 PM, PCT 6 was observed at station 23. PCT 6, donned gloves and failed to perform hand hygiene prior to donning the gloves and reset the alarm on the machine.</p> <p>16. During an observation on 8/23/2023 at 11:07 AM, PCT 6 was observed initiating dialysis and performing exit site care. PCT 6 failed to perform any hand hygiene or glove changes during the procedure, PCT 6 failed to remove her gloves and sanitize her hands after removing the dressing, remove her gloves and sanitize her hands after applying the sterile dressing, and failed to remove her gloves and sanitize her</p>	V 113			

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V 113	Continued From page 10 hands before placing a clean field under the catheter. 17. During an observation on 8/24/2023 at 12:02 PM, Nurse 3 retrieved gloves from the clean box donned the gloves and was priming the machine lines at station 3. Nurse 3 failed to wash or sanitize her hands prior to donning the gloves. During an interview on 8/23/2023 at 2:45 PM, The Facility Administrator indicated handwashing should be done when hands are visibly dirty or between patient contact using soap and water. She indicated this procedure should take 60-90 seconds; She indicated when using hand sanitizer hands should be rubbed together until the sanitizer is dry.	V 113			
V 115	IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK CFR(s): 494.30(a)(1)(i) Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurling or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review and interview the facility failed to ensure they followed their policies and procedures regarding the proper use of Protective equipment for patients and staff members on the treatment floor.	V 115			

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V 115	Continued From page 11 The Finding Includes: An agency policy titled "Personal Protective Equipment," published 2/14/2023, stated, "Personal protective equipment such as a full face shield or mask and protective eyewear with full side shield ... will be worn to protect and prevent employees from blood or other potentially infectious materials to pass through to or reach the employee skin, eyes, mouth, other mucous membranes, or work clothes when performing procedures during which spurting or splattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood) ... In Designated patient care activities in areas at risk for blood splatter or spill ... a full face shield or mask and protective eyewear with full side shield should be worn" During an observation on 8/23/2023 at 2:20 PM, RN 2 was at station 22 checking Patient #29's Central Venous Catheter (CVC), during her treatment. As RN 2 failed to put on her face shield before close contact with the CVC that had blood running through it. During an interview at 2:49 PM, the Facility Administrator indicated anytime staff could be splashed with blood or bodily fluid they should be wearing eye protection. When informing her of the findings she indicated RN 2 should have been wearing eye protection when handling the CVC.	V 115			
V 116	IC-IF TO STATION=DISP/DEDICATE OR DISINFECT CFR(s): 494.30(a)(1)(i) Items taken into the dialysis station should either be disposed of, dedicated for use only on a single	V 116			

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V 116	<p>Continued From page 12</p> <p>patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.</p> <p>-- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.</p> <p>-- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the dialysis facility failed to ensure all items were clean and disinfected before being placed a common clean area.</p> <p>The findings include:</p> <p>An observation in the treatment area on 8/23/2023 at 2:05 PM revealed Patient #26 removed a tablet (computer) from an open cabinet located below a countertop labeled as "dirty". Patient #26 looked at the tablet, placed it on the "dirty" countertop, retrieved an additional tablet from the cabinet, then removed the first tablet from the "dirty" countertop, and placed it back into the cabinet.</p> <p>During an interview on 8/23/2023 at 3:38 PM, the Facility Administrator indicated the tablets should be disinfected with bleach after patient use. The Director of Operations, Area Tech Operations Manager, and the Facility Administrator all indicated the cabinet should be locked and</p>	V 116			

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

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152520	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 08/29/2023
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V 116	Continued From page 13	V 116			
V 122	<p>patients shouldn't have access to the tablets.</p> <p>IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL CFR(s): 494.30(a)(4)(ii)</p> <p>[The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the dialysis facility staff failed to ensure all equipment and potentially contaminated surfaces were properly cleaned and disinfected.</p> <p>The findings include:</p> <p>1. An agency document titled "Cleaning and Disinfecting of the Dialysis Station Procedure." published 11/4/2019, stated " ... Use a cloth wetted with 1:100 bleach solution or EPA dash approved disinfectant to clean and disinfect the dialysis station (chair slash bed, tables, machine, television, IV pole, BP cuff, hand sanitizers dispenser and holder, etc.). Place the chair in Trendelenburg position and open side tunnels if chair has swing open side so all surfaces of the chair are accessible. 4. Clean all surfaces. Make the surfaces glisteningly wet and allow to air dry unless otherwise specified by the manufacturer.5. Give special attention to cleaning control panel on the dialysis machine and other surfaces that are</p>	V 122			

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V 122	Continued From page 14 frequently touched and potentially contaminated with patients' blood and slash or bodily fluids. While wiping, remember to wipe all the surfaces of the machine including the air detector chamber, blood pump casing, IV pole, and wherever the extracorporeal circuit was in contact with the machine" 2. During an observation on 8/22/2023 at 11:12 AM (station 7), PCT 7 failed to clean/disinfect the top of the intravenous (IV) pole, or the shelf behind the dialysis machine. 3. An observation on 8/22/2023 at 2:50 PM (station 2) revealed PCT 7 failed to clean/disinfect the top of the intravenous (IV) pole or the shelf behind the dialysis machine, and then placed the disinfected removable arm cushion on the shelf. 4. During an observation on 8/22/2023 at 11:28 PM, Patient Care Technician (PCT) 5 was observed cleaning station 17. PCT 5 failed to clean the IV pole and hung the clean TV remote on the dirty IV pole. During an interview on 8/23/2023 at 3:00 PM, The Facility Administrator indicated when cleaning the dialysis station everything should be cleaned with bleach cloths including the IV pole that is attached to the machine.	V 122			
V 143	IC-ASEPTIC TECHNIQUES FOR IV MEDS CFR(s): 494.30(b)(2) [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and	V 143			

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V 143	Continued From page 15 This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the dialysis facility failed to ensure the staff wiped the stopper of a multi-dose medication vial with an alcohol wipe for 2 of 2 observations of medication administration. (PCT 3, RN 2) The findings include: 1. An agency policy titled "Medication Preparation and Administration Procedure, " published 2/6/2023, stated " ... Cleanse the diaphragm of the vial with alcohol prior to accessing the vial. If the vial is multidose, 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 the vial. 2. During an observation of medication preparation and administration on 8/22/2023 at 11:16 AM, PCT 3, was observed to draw up Heparin (used to prevent blood clots) from a multi-dose vial by inserting two sterile needles into the stopper of the vial and withdrawing the heparin medication into the syringes. PCT 3 failed to wipe the opened heparin vial with an alcohol pad prior to inserting the second syringe needle into the vial. PCT 3 was then observed to take the syringes to station 19 for administration. 3. During an observation of medication preparation and administration on 8/22/2023 at 11:19 AM, RN 2, was observed to draw up Heparin. RN 2 used an alcohol wipe and swiped the top of the hub on the vial one time, failing to use friction, and drew up the medication. RN 2	V 143			

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V 143	Continued From page 16 opened a second bottle of Heparin and swiped the top with an alcohol pad one time failing to use friction.	V 143			
V 147	During an interview on 8/23/2023 at 2:57 PM, the Facility Administrator indicated the rubber stopper of the vial should be cleaned with alcohol using friction before each needle insertion. IC-STAFF EDUCATION-CATHETERS/CATHETER CARE CFR(s): 494.30(a)(2) Recommendations for Placement of Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters. II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients. VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use	V 147			

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V 147	<p>Continued From page 17</p> <p>antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview the agency failed to ensure proper procedures were used to prevent infections in 1 of 2 observations of initiation and discontinuation of treatment for patients with a Central Venous Catheter, (CVC). (PCT 6)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. An agency policy titled "Initiation of Treatment Using a Central Venous Catheter" published 7/6/2021, stated " ... Threads and end of the hub must be scrubbed with an alcohol pad for 15 seconds and anytime caps are removed, or bloodlines are disconnected to reduce the risk of contamination...." 2. During an observation on 8/23/2023 at 11:01 AM, PCT 6 was observed at station 22 discontinuing dialysis through a CVC for Patient #8. PCT 6 scrubbed the venous hub for 9 seconds and scrubbed the arterial hub for 9 seconds, failing to scrub for at least 15 seconds. <p>During an interview on 8/24/2023 at 3:47 PM, the Facility Administrator indicated staff should scrub the hubs on the CVC for at least 30 seconds.</p> <ol style="list-style-type: none"> 3. An observation on 8/23/2023 at 11:15 AM revealed the presence of dried blood on Patient #6's (station 18) disposable field between the central venous catheter (CVC) tubing/ports and the patient's clothing. Upon initiation of the 	V 147			

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V 147	Continued From page 18 discontinuation of dialysis, the Charge Nurse failed to place a new clean field under the CVC ports.	V 147			
V 403	PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU CFR(s): 494.60(b) The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This STANDARD is not met as evidenced by: Based on observation and interview, the dialysis facility failed to ensure emergency equipment and/or supplies in the emergency cart were maintained per manufacturer's instructions and/or agency policy. The findings include: 1. An agency policy titled "Expiration Dates Sterile Supplies," published 7/4/2012, stated, "Appropriately dispose of sterile items that have reached their expiration date...." 2. An observation in the treatment area on 8/22/2023 at 9:46 AM revealed a previously opened bottle of hydrogen peroxide located on the top of the emergency cart, which was expired as of 9/2020. Observation of the contents of the cart revealed a previously opened bottle of clonidine tablets, but failed to evidence the bottle was marked with the date it was opened.	V 403			

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V 403	Continued From page 19 3. During an observation on 8/22/2023 at 9:56 AM, emergency medications and supplies were observed locked in the emergency evacuation cart. There were 3 transparent dressings with an expiration date of 4/2022. The agency failed to ensure expired supplies were removed from the cart. 4. During an interview on 8/22/2023 at 9:46 AM, the facility Administrator indicated the carts were due to be checked today. She indicated expired medications should be removed. She also indicated the medications should be dated and initialed when opened.	V 403			
V 407	PE-HD PTS IN VIEW DURING TREATMENTS CFR(s): 494.60(c)(4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). This STANDARD is not met as evidenced by: Based on observation, record review and interview, the dialysis facility failed to ensure all patients' vascular access sites and/or bloodline connections were visible throughout the dialysis treatment. The findings include: 1. An agency policy titled "Patient Assessment and Monitoring" published 5/1/2023 stated " ... Ensure the access remains uncovered throughout the entire treatment...." 2. An observation in the treatment area on	V 407			

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V 407	<p>Continued From page 20</p> <p>8/22/2023 at 9:40 AM revealed Patient #10's (station 5) vascular access site was covered, and not readily visible during dialysis treatment.</p> <p>3. An observation in the treatment area on 8/22/2023 at 9:41 AM revealed Patient #11's (station 3) vascular access site was covered, and not readily visible during dialysis treatment.</p> <p>4. An observation in the treatment area on 8/24/2023 at 11:25 AM revealed Patient #18's (station 14) vascular access site was covered with a throw blanket, and not readily visible during dialysis treatment. At 12:02 PM, Patient #18's vascular access site remained covered with a throw blanket.</p> <p>5. During an observation on 8/22/2023 at 2:49 M, Patient #13 at station 13 had his access covered with a blanket. The access was still covered at 3:45 PM. The agency failed to ensure Patient access sites remain uncovered during treatment.</p> <p>6. During an observation on 8/22/2023 at 3:00 AM, Patient #14 at station 12 had her access covered with a blanket. The agency failed to ensure Patient access sites remain uncovered during treatment.</p> <p>7. During an observation on 8/23/2023 at 1:35 PM, Patient #15 at station 21 had her access covered with a blanket. The access was still covered at 2:15 PM. The agency failed to ensure Patient access sites remain uncovered during treatment.</p> <p>8. During an observation on 8/23/2023 at 1:35 PM, Patient #16 at station 22 had her access covered with a blanket. The access was still</p>	V 407			

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V 407	Continued From page 21 covered at 2:00 PM. The agency failed to ensure Patient access sites remain uncovered during treatment. 9. During an observation on 8/23/2023 at 1:36 PM, Patient #30 at station 16 had his access covered with a blanket. The access was still covered at 2:00 PM. The agency failed to ensure Patient access sites remain uncovered during treatment. 10. During an observation on 8/23/2023 at 1:37 PM, Patient #31 at station 1 had his access covered with a blanket. The access was still covered at 2:10 PM. The agency failed to ensure Patient access sites remain uncovered during treatment. 11. During an observation on 8/23/2023 at 1:37 PM, Patient #32 at station 2 had his access covered with a blanket. The access was still covered at 2:17 PM. The agency failed to ensure Patient access sites remain uncovered during treatment. 12. During an observation on 8/24/2023 at 11:24 AM, Patient #34 at station 14 had his access covered with a blanket. The access was still covered at 12:02 PM. The agency failed to ensure Patient access sites remain uncovered during treatment. During an interview on 8/23/2023 at 2:57 PM, the Facility Administrator indicated the Patients' access should never be covered.	V 407			
V 452	PR-RESPECT & DIGNITY CFR(s): 494.70(a)(1)	V 452			

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V 452	Continued From page 22 The patient has the right to- (1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD This STANDARD is not met as evidenced by: Based on observation and interview, the dialysis facility failed to maintain the patient's right to respect and dignity for 1 of 1 random patient observed (#27). The findings include: During a random observation on 8/22/2023 at 11:12 AM, Patient #27 completed dialysis treatment and was leaving the facility. Observed dressings over the vascular access sites on the left upper arm, multiple visible blood smears all over the left upper arm, and large, fresh, bright red blood stains on the left lateral side of the patient's pants. The dialysis facility staff failed to ensure the patient was free of visible blood on skin and clothing before leaving the dialysis facility. During an interview on 8/22/2023 at 2:34 PM, the Facility Administrator indicated the Patient's arm should have been cleaned with soap and water. She also indicated they have paper scrubs that can be offered to Patient's to put over their clothes if they get blood on them.	V 452			
V 500	CFC-PATIENT ASSESSMENT CFR(s): 494.80	V 500			

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V 500	Continued From page 23 This CONDITION is not met as evidenced by: Based on observation, record review and interview the dialysis center failed to ensure the interdisciplinary team (IDT) members completed a comprehensive interdisciplinary assessments (V501), failed to ensure the interdisciplinary team assessed and met the needs of patients, failed to ensure the appropriateness of dialysis prescriptions (see tag 503), and failed to ensure blood pressure and fluid management needs were met (see tag 504), failed to ensure an initial comprehensive assessment was conducted within 30 calendar days or within 13 hemodialysis sessions (V516), failed to ensure a comprehensive reassessment of the patient occurred and/or a revision of the plan of care was made (V520). The cumulative effect of these systemic problems has resulted in the dialysis center's inability to ensure the provision of quality health care in a safe environment for the condition of participation 42CFR 494.80 Patient Assessment.	V 500			
V 501	PA-IDT MEMBERS/RESPONSIBILITIES CFR(s): 494.80 The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.	V 501			

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V 501	Continued From page 24 This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to ensure the interdisciplinary team members completed comprehensive interdisciplinary assessments for 1 of 1 clinical record reviewed for a patient recently transferred to the facility. The findings include: Record review for Patient #7 (admit date 6/19/2023) evidenced the patient recently transferred from a facility in another state, and failed to evidence any comprehensive interdisciplinary assessments were conducted by a Registered Nurse, Social Worker, or Dietician. During an interview on 8/25/2023 at 2:38 PM, the Regional Social Work Manager (corporate) indicated they were out of compliance, they should have had interdisciplinary team meetings, and completed comprehensive interdisciplinary assessments.	V 501			
V 503	PA-APPROPRIATENESS OF DIALYSIS RX CFR(s): 494.80(a)(2) The patient's comprehensive assessment must include, but is not limited to, the following: (2) Evaluation of the appropriateness of the dialysis prescription, This STANDARD is not met as evidenced by: Based on observation, record review, and	V 503			

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V 503	<p>Continued From page 25</p> <p>interview the agency failed to ensure the physician was notified of changes in conditions and failed to ensure the appropriateness of the patient's dialysis prescriptions in 5 of 7 records reviewed. (Patient #1, #2, #3, #4, #6)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. An agency document titled "Patient Assessment and Monitoring," published 5/1/2023, stated, " ... If the PCT/LPN [patient care technician/licensed practical nurse] notes any changes or abnormal findings in the patient's condition, the patient care technician must report the findings to the registered nurse [RN] who will further assess the patient ... During nursing rounds will assess the following parameters ... auscultate lung sounds ... assess for edema ... contact the Physician as needed for additional orders based on assessment findings and clinical judgment" 2. Clinical record review on 8/24/2023 for Patient #1, start of care 8/19/2022, included a review of the dialysis treatment sheets from 7/26/2023 through 8/21/2023 and evidenced the following: The flowsheets dated 7/31/2023, 8/4/2023, 8/11/2023, 8/11/2023, and 8/21/2023 documented Patient #1 had decreased breath sounds and edema to the lower extremities. The agency failed to notify the Physician of Patient #1's assessment findings. 3. Clinical record review on 8/24/2023 for Patient #2, start of care 2/7/2023, included a review of the dialysis treatment sheets from 7/25/2023 through 8/19/2023 and evidenced the following: 	V 503			

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA			STREET ADDRESS, CITY, STATE, ZIP CODE 710 PARK PL MISHAWAKA, IN 46545		
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V 503	<p>Continued From page 26</p> <p>The flowsheet dated 7/25/2023 documented Patient #2 had complaints of diarrhea and the dietician was notified. The documentation failed to evidence the Physician was notified of the Patient's complaints of diarrhea.</p> <p>The flowsheets dated 7/25/2023 and 7/27/2023 documented Patient #2 had edema (swelling) in the right ankle. The edema caused a 4-6 mm (millimeter) indent lasting more than a minute when the ankle was pressed.</p> <p>The flowsheet dated 7/27/2023 documented Patient #2 had complaints of nausea and the dietician was notified. The documentation failed to evidence the Physician was notified of the Patient's complaints of nausea.</p> <p>The flowsheet dated 7/29/2023 documented Patient #2 had gross edema of the right leg. The documentation failed to evidence the Physician was notified of the Patient's edema.</p> <p>The flowsheet dated 8/3/2023 documented Patient #2 had complaints of pain in the neck and shoulder. The documentation failed to evidence the Physician was notified of the Patient's complaints of pain.</p> <p>The flowsheet dated 8/8/2023 documented Patient #2 had complaints she couldn't breathe. BP was low and RN gave 100 ml of saline. The documentation failed to evidence the Physician was notified of the Patient's change in condition.</p> <p>The flowsheet dated 8/10/2023 documented Patient #2 had edema in the right ankle and lower leg. The edema caused a 4-6 mm (millimeter) indent lasting more than a minute when the ankle and leg were pressed.</p>	V 503			

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V 503	Continued From page 27 4. Clinical record review on 8/24/2023 for Patient #3, start of care 5/16/2019, included a review of the dialysis treatment sheets from 7/28/2023 through 8/21/2023 and evidenced the following: The flowsheet dated 7/26/2023 documented at 11:54 AM, Patient #3 had complaints of the room spinning and 100 ml of saline was given, at 1:33 PM patient complained of cramping and 100 ml of saline given. The documentation failed to evidence the Physician was notified of the Patient's change in condition. The flowsheet dated 8/14/2023 documented at 2:32 AM, Patient #3 had complaints of cramping in her hands 100 ml of saline was given, at 4:55 PM, Patient #3 requested to come off treatment early due to cramping, and 500 ml of saline was given, and treatment was discontinued. The documentation failed to evidence the Physician was notified of the Patient's change in condition. 5. Clinical record review on 8/24/2023 for Patient #4, start of care 2/1/2022, included a review of the dialysis treatment sheets from 5/4/2023 through 5/30/2023 and evidenced the following: The flowsheet dated 5/16/2023 documented Patient #4 had complaints of cramping toward the end of treatment and 200 ml of fluid was given. The documentation failed to evidence the Physician was notified of the Patient's cramping. The flowsheet dated 5/16/2023 documented Patient #4 had complaints of cramping in the right leg. The documentation failed to evidence the Physician was notified of the Patient's cramping.	V 503			

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V 503	Continued From page 28 During an interview on 8/28/2023 at 3:35 PM the Facility Administrator indicated the nurses use clinical judgment on when to report findings to the Physician. 6. Record review for Patient #6 (admit date 8/05/2022) evidenced a physician progress note, dated 8/11/2023, evidenced the patient's EDW was increased to 90 kg (not specified date of increase) and an entry within the note, dated 7/26/2023, evidenced the patient recently relocated from another state.	V 503			
V 504	PA-ASSESS B/P, FLUID MANAGEMENT NEEDS CFR(s): 494.80(a)(2) The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs. This STANDARD is not met as evidenced by: Based on observation, record review, and interview the dialysis facility failed to ensure patient pre, during, post and intradialytic blood pressure were being assessed and managed in 6 of 7 hemodialysis records reviewed. (Patient #1, #2, #3, #4, #5, #7) 1. An agency document titled "Patient Assessment and Monitoring," published 5/1/2023, stated, " ... If the PCT/LPN [patient care technician/licensed practical nurse] notes any changes or abnormal findings in the patient's condition, the registered nurse [RN] must assess the patient ... Report to the nurse systolic blood pressures greater than 180 diastolic blood	V 504			

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V 504	<p>Continued From page 29</p> <p>pressures greater than 100 systolic pressures less than or equal to 100 during treatment ... Report to the nurse patients whose heart rates have dropped below 60 or have risen above 100 ... An abnormal finding confirmed by the RN will be reported to the attending physician if necessary...."</p> <p>2. An agency policy titled "Volume Management in ESRD [End Stage Renal Disease] Patients on Hemodialysis" published 9/7/2021 stated, "If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with the physician for appropriate fluid interventions: Pre-treatment sitting systolic BP is greater than 160 mmHg and prior treatment post dialysis sitting systolic BP is greater than 140 mmHg...."</p> <p>3. An agency policy titled "Nursing Supervision and Delegation," published 5/1/2023, stated, " ... The following can be used as a guideline for the PCT/ LPN or RN to refer the patient to the charge nurse for further assessment The charge nurse will determine any clinical interventions needed ... A systolic blood pressure greater than 180 and/or diastolic blood pressure greater than 100 at any time before, during or after the treatment. If B/P [blood pressure] less than 100 systolic during treatment A systolic blood pressure less than 100 post-treatment when standing. A drop in systolic BP of 20 between sitting and standing...."</p> <p>4. Record review for Patient #7 (admit date 6/19/2023) evidenced a physician progress note dated 5/19/2023, from the patient's previous dialysis facility (Entity 1) which failed to be received by the current dialysis facility until 8/25/2023. The note indicated the patient's</p>	V 504			

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V 504	<p>Continued From page 30</p> <p>estimated dry weight (EDW) was 84 kilograms (kg), blood pressure was stable, and fluid status was acceptable.</p> <p>A review of a nutrition progress note dated 7/12/2023, indicated the patient transferred from another state, took an appetite supplement, had a hard time eating due to rotten bottom teeth, currently took an antibiotic for an infected tooth, which caused gastrointestinal (GI) upset; took Tums to manage GI upset (causes low phosphorus levels), and was instructed to stop use of Tums. The progress note also evidenced the patient's laboratory values on 7/03/2023, were as follows: albumin level was below goal at 3.6 (normal range for dialysis patient is preferred to be greater than 4.0, and indicates decreased protein intake/poor nutrition); phosphorus level was below goal at 1.8 (normal range for dialysis patient is preferred to be 3.5 - 5.5, indicates possible overuse of certain antacids, and can cause loss of appetite, fragile bones, weakness, and weight change); equilibrated normalized protein catabolic rate (enPCR) was below goal at 0.86 grams per kilogram per day (g/kg/day) (less than 1.0 is low, and indicates decreased protein intake/nutritional status); and the nutrition plan was to collaborate with the interdisciplinary team (IDT), continue the current plan of care (POC), and the care plan goals were reviewed/updated. The clinical record failed to evidence collaboration with the IDT occurred, any comprehensive interdisciplinary assessments (CIAs) were conducted by a Registered Nurse (RN), Social Worker (SW), or Dietician; or a plan of care was created, reviewed, or updated for the patient.</p> <p>A physician's order dated 6/19/2023, evidenced a</p>	V 504			

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V 504	<p>Continued From page 31</p> <p>medication order to administer Midodrine (to treat low blood pressure) 5 milligrams (mg) as needed for symptomatic (such as dizziness, lightheadedness, weakness) systolic (top number) blood pressure (SBP) less than 100.</p> <p>A dialysis treatment sheet dated 7/17/2023, evidenced the dialysis prescription included (but was not limited to): EDW 86.0 kg. Pre-treatment weight was 90.1 kg, and post-treatment weight was 87.3 kg (1.3 kg over EDW). Pre-treatment sitting blood pressure at 12:41 PM was 108 (systolic)/48 (diastolic). During treatment, blood pressures were (but not limited to): 12:50 PM- 101/46, 1:32 PM-102/45, 2:04 PM- 101/43, 2:33 PM- 108/47, and 3:04 PM- 112/48. A RN evaluation was performed at 12:59 PM, which indicated "no unusual findings noted". Midodrine was administered at 2:42 PM by a RN, although SBP wasn't less than 100. No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 7/19/2023, evidenced the dialysis prescription included: EDW 86.0 kg, and dialysate flow rate (DFR) (speed of fluid passing through the dialysis machine during treatment) was manual 800 milliliters per minute (ml/min). Pre-treatment weight was 89.8 kg, and post-treatment weight was 87.8 kg. Pre-treatment sitting blood pressure at 12:31 PM was 95/42. During treatment, blood pressures were: 12:48 PM- 99/42, 1:04 PM-107/43, 1:32 PM- 106/47, and 4:04 PM- 118/48. DFR was set and ran at 500 ml/min throughout treatment. A RN evaluation was performed at 12:47 PM, which indicated "no unusual findings noted". Midodrine was</p>	V 504			

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V 504	<p>Continued From page 32</p> <p>administered at 12:46 PM by a RN. No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, the decreased DFR, or the unmet EDW.</p> <p>VA physician progress note dated 7/21/2023, evidenced the patient's EDW was 86.0 kg, the patient reported he was doing good, and had no issues; and a late entry within the document was dated as effective on 7/12/2023, which evidenced blood pressure was controlled, and EDW was stable.</p> <p>A dialysis treatment sheet dated 7/21/2023, evidenced the dialysis prescription included EDW 86.0 kg. Pre-treatment weight was 90.0 kg, and post-treatment weight was 87.2 kg. Pre-treatment sitting blood pressure at 12:38 PM was 129/59. During treatment, blood pressures were: 1:03 PM-138/75, 1:35 PM- 164/69, 3:40 PM-187/90, and 4:06 PM- 195/87. A RN evaluation was performed at 12:40 PM, which indicated "no unusual findings noted". No further RN assessments were made, and the physician wasn't notified of the high blood pressure readings for this patient, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 7/24/2023, evidenced the dialysis prescription included: EDW 86.0 kg, blood flow rate (BFR) 400, DFR manual 800 ml/min. Pre-treatment weight was 91.4 kg, and post-treatment weight was 87.9 kg. Pre-treatment sitting blood pressure at 12:34 PM was 140/57. During treatment, blood pressures were: 1:12 PM-110/49, 1:31 PM- 108/48, and 3:02 PM- 134/49. BFR and DFR were both set and ran at 500 ml/min throughout treatment. A RN evaluation was performed at 12:32 PM, which</p>	V 504			

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V 504	<p>Continued From page 33</p> <p>indicated "no unusual findings noted". Venofer (supplemental iron) was administered at 12:50 PM by a RN. No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, the increased BFR, the decreased DFR, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 7/26/2023, evidenced the dialysis prescription included: EDW 86.0 kg, BFR 400, and DFR manual 800 ml/min. Pre-treatment weight was 91.5 kg, and post-treatment weight was 88.9 kg. Pre-treatment sitting blood pressure at 12:23 PM was 98/45. During treatment, blood pressures, BFR, and/or DFR were: 12:39 PM-103/50, BFR 300, DFR 500; 1:04 PM, 1:39 PM, and 2:03 PM- BFR 300, DFR 500; 2:34 PM and 3:09 PM- BFR 400, DFR 500; 3:37 PM- BFR 500, DFR 500. A RN evaluation was performed at 12:30 PM, which indicated Midodrine was given prior to treatment for "slight hypotension" (low blood pressure). Midodrine was administered at 12:29 PM by a RN. No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, the administration of unprescribed BFR and DFR, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 7/28/2023, evidenced the dialysis prescription included: EDW 86.0 kg, BFR 400, and DFR manual 800 ml/min. Pre-treatment weight was 91.7 kg, and post-treatment weight was 88.6 kg. Pre-treatment sitting blood pressure at 12:32 PM was 101/46. During treatment, BFR ran at 500 ml/min, and blood pressures were: 1:03 PM- 102/46, and 1:32 PM- 111/48. Weekly Venofer was due for administration (last dose 7/21/2023), but not administered. Midodrine was administered at 12:50 PM, by a RN, although SBP wasn't below</p>	V 504			

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V 504	<p>Continued From page 34</p> <p>100. A RN evaluation was performed at 12:58 PM, which indicated that he felt short of breath. No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, the shortness of breath, the administration of unprescribed BFR, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 7/31/2023, evidenced the dialysis prescription included: EDW 86.0 kg, BFR 400 ml/min, and DFR manual 800 ml/min. Pre-treatment weight was 92.3 kg, and post-treatment weight was 89.5 kg. Pre-treatment sitting blood pressure at 12:39 PM was 107/73. During treatment, DFR ran at 500 ml/min, and blood pressures were: 1:09 PM- 103/46, 1:33 PM- 91/41, 2:00 PM- 101/47, 3:06- 98/42, no blood pressure assessments again until 4:13 PM- 115/48. Weekly Venofer was administered. A RN evaluation was performed at 12:54 PM, which indicated "no unusual findings noted". Midodrine was administered at 12:57 PM by a RN. No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, the administration of unprescribed DFR, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 8/02/2023, evidenced the dialysis prescription included: EDW 86.0 kg, BFR 400 ml/min, and DFR manual 800 ml/min. Pre-treatment weight was 91.7 kg, and post-treatment weight was 90.4 kg. Pre-treatment sitting blood pressure at 12:37 PM was 103/44. During treatment, blood pressures were: 12:39 PM- 92/41, 1:10 PM- 96/42, 1:32- 89/41, 1:44 PM- 98/44, 2:02 PM- 106/46, and 2:35 111/46. Midodrine was administered at 1:40 PM by a RN. A RN evaluation was performed at 1:41 PM, which indicated the patient ambulated</p>	V 504			

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V 504	<p>Continued From page 35</p> <p>without assistance, and had no complaints. No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 8/04/2023, evidenced the dialysis prescription included: EDW 86.0 kg, BFR 400 ml/min, and DFR manual 800 ml/min. Pre-treatment weight was 92.6 kg, and post-treatment weight was 91.2 kg. Pre-treatment sitting blood pressure at 12:39 PM was 109/55. During treatment, blood pressures were: 1:33 PM- 99/42, 2:05 PM- 98/44, 2:38 PM- 98/41, 3:32 PM- 102/42, 4:02 PM- 103/45, and post-treatment blood pressure was 110/43. Midodrine wasn't administered for systolic blood pressures under 100. RN evaluations were performed at 3:03 PM and 3:04 PM. No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 8/07/2023, evidenced the dialysis prescription included: new EDW increased to 90.0 kg, BFR 400 ml/min, and DFR manual 800 ml/min. Pre-treatment weight was 95.1 kg, and post-treatment weight was 92.4 kg. Pre-treatment sitting blood pressure at 12:39 PM was 114/54. Post-treatment blood pressure was 111/45. A RN evaluation was performed at 3:37 PM, which indicated the patient was now non-ambulatory, and used a wheelchair. No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, the change in ambulatory status, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 8/09/2023, evidenced the dialysis prescription included:</p>	V 504			

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V 504	<p>Continued From page 36</p> <p>EDW 90.0 kg, BFR 400 ml/min, and DFR manual 800 ml/min. Pre-treatment weight was 95.0 kg, and post-treatment weight was 91.7 kg. Pre-treatment sitting blood pressure at 12:38 PM was 93/38. BFR set and ran at 500 ml/min. Midodrine was administered at 12:45 PM by a RN. Post-treatment blood pressure was 109/48. A RN evaluation was performed at 12:46 PM, which indicated "no unusual findings noted". No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, the administration of unprescribed BFR, or the unmet EDW.</p> <p>A physician progress note, dated 8/11/2023, evidenced the patient's EDW was increased to 90 kg and an entry within the note, dated 7/26/2023, evidenced the patient recently relocated from another state.</p> <p>A dialysis treatment sheet dated 8/11/2023, evidenced the dialysis prescription included: EDW 90.0 kg, BFR 400 ml/min, and DFR manual 800 ml/min. Pre-treatment weight was 93.9 kg, and post-treatment weight was 91.6 kg. Pre-treatment sitting blood pressure at 12:29 PM was 99/48. Midodrine was administered at 12:37 PM by a RN. Post-treatment blood pressure was 101/47. A RN evaluation was performed at 12:38 PM, which indicated the patient could transfer himself. No further RN assessments were made, and the physician wasn't notified of the low blood pressure readings, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 8/14/2023, evidenced the dialysis prescription included: EDW 90.0 kg, BFR 400 ml/min, and DFR manual 800 ml/min. Pre-treatment weight was 95.8 kg, and post-treatment weight was 93.9 kg.</p>	V 504			

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

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152520	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 08/29/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA			STREET ADDRESS, CITY, STATE, ZIP CODE 710 PARK PL MISHAWAKA, IN 46545		
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V 504	<p>Continued From page 37</p> <p>Pre-treatment sitting blood pressure at 12:48 PM was 91/44. A RN evaluation was performed at 12:47 PM, which indicated "no unusual findings noted". No further RN assessments were made. During treatment, blood pressures were: 12:57 PM- 90/51, 1:10 PM- 91/44, 1:40- 77/44, 1:48- 88/42, 2:03- 97/48, and 2:33 PM 96/51. Post-treatment blood pressure was 101/47. The physician wasn't notified of the low blood pressure readings, or the unmet EDW.</p> <p>A physician's order dated 8/16/2023, evidenced a medication order to administer Midodrine 10 mg as needed for systolic blood pressure less than 100.</p> <p>A dialysis treatment sheet dated 8/18/2023, evidenced the dialysis prescription included: EDW 90.0 kg, BFR 400 ml/min, and DFR manual 800 ml/min. Pre-treatment weight was 96.4 kg, and post-treatment weight was 93.7 kg. Pre-treatment sitting blood pressure at 12:47 PM was 110/52. No further blood pressures were documented until 1:05 PM (105/43). Midodrine was administered at 12:59 PM. A RN evaluation was performed at 12:59 PM, which indicated "no unusual findings noted". No further RN assessments were made. Post-treatment blood pressure was 119/57. The physician failed to be notified of the low blood pressure readings, or the unmet EDW.</p> <p>A dialysis treatment sheet dated 8/21/2023, evidenced the dialysis prescription included: EDW 90.0 kg, BFR 400 ml/min, and DFR manual 800 ml/min. Pre-treatment weight was 98.4 kg, and post-treatment weight was 95.7 kg. Pre-treatment sitting blood pressure at 12:36 PM was 102/49. A RN evaluation was performed at</p>	V 504			

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V 504	<p>Continued From page 38</p> <p>1:03 PM, which indicated the patient had worsened bilateral lower leg and ankle edema, the physician was notified with recommendation to add 15 minutes to today's dialysis treatment, and adjust total target weight removal to maximum hourly ultra-filtration rate (UFR) (speed at which fluid is removed to attain target weight), and the physician declined both recommendations. No further RN assessments were made. During treatment, blood pressures were: 12:40 PM- 99/45, 1:06 PM 99/45, and 4:06 PM- 111/46. Post-treatment blood pressure at 4:08 PM was 109/37.</p> <p>A fall report document received from Entity 2 on 8/28/2023, dated 8/22/2023, indicated Entity 2 staff found Patient #7 on the floor in his apartment bedroom, with a compound fracture of the left shin bone; the patient stated that he stood up from the bed, became weak, and fell to the floor; predisposing factors included low blood pressure and weakness/fainted; and was sent to Entity 3 (hospital emergency department [ED]).</p> <p>A staff progress note document received from Entity 2 on 8/28/2023, evidenced an entry dated 8/22/2023, at 9:01 AM, which indicated the patient fell in his room with injuries; an entry dated 8/22/2023 at 11:08 AM, evidenced family was present with the patient in the ED; and an entry dated 8/22/2023 at 1:31 PM, indicated family reported the patient passed away at 12:20 PM, with family by his side.</p> <p>During an interview on 8/24/2023 at 3:15 PM, the Facility Administrator (FA) indicated if dialysis settings were not ran as ordered, it should be documented why it was not, and the RN should be notified; the RN should assess the patient</p>	V 504			

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V 504	<p>Continued From page 39</p> <p>before and after dialysis treatments, for any issues during treatment, and assessments should include at least edema, neurological and respiratory statuses, lung sounds, or something abnormal. The Director of Operations indicated there was a basic assessment that would pull over to the treatment sheet if it was done.</p> <p>During an interview on 8/25/2023 at 11:40 AM, the FA indicated there were no treatment notes 8/23/2023 to present, because the patient died Wednesday (8/23/2023), they didn't have a plan of care because they had 90 days to do one, they didn't receive a plan of care from Entity 1 when the patient transferred from their facility to this one, but she would call them and have them fax one.</p> <p>During an interview on 8/25/2023 at 2:38 PM, the Regional Social Work Manager indicated they were out of compliance with the plan of care, they should have had IDT meetings, completed CIAs, and created a POC. The Dietician indicated the patient should have been listed as unstable, due to his condition. The Charge Nurse indicated the patient moved up here to be with family because he had declined so much, and he would have probably benefited from hospice services.</p> <p>During an interview on 8/25/2023 at 3:08 PM, Person 1 (staff at Entity 1) indicated Patient #7 stood up, and because of weakness, fell directly to the ground, sustained a compound fracture (an open wound or break in the skin near the site of the broken bone), she believed it was his left lower leg, he's been on dialysis, last Friday (8/18/2023) he said he was giving up, and didn't know if he wanted to continue. Person 1 also indicated the patient passed away while at the</p>	V 504			

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V 504	<p>Continued From page 40 hospital.</p> <p>5. Record review for patient #5 (admit date 5/26/2020) evidenced treatment sheets dated July 25, 27, 29 (2023), and August 1, 8, 10, 12, 15, 17, and 19 (2023), which all evidenced the patient was/became hypotensive (low blood pressure); but failed to evidence the Patient Care Technician(s) (PCT) notified the Registered Nurse (RN).</p> <p>6. Clinical record review on 8/24/2023 for Patient #1, start of care 8/19/2022, included a review of the dialysis treatment sheets from 7/26/2023 through 8/18/2023 and evidenced the following:</p> <p>The Flowsheet dated 7/28/2023 documented Patient #1's pretreatment sitting blood pressure (BP), was 174/98 and his prior treatment (7/21/2023) sitting BP was 163/74. The agency failed to follow policies and procedures and failed to notify the Nurse and Physician of Patient #1's pretreatment blood pressure.</p> <p>The Flowsheet dated 8/7/2023 documented Patient #1's pretreatment sitting BP, was 190/94. The agency failed to follow policies and procedures and failed to notify the Nurse and Physician of Patient #1's pretreatment blood pressure.</p> <p>The Flowsheet dated 8/11/2023 documented Patient #1's pretreatment sitting BP, was 178/95, heart rate (HR) 110 and irregular, and his prior treatment (8/7/2023) sitting BP was 158/82; at 11:46 AM, HR was 106; at 12:35 PM, HR was 107. The agency failed to follow policies and procedures and failed to notify the Nurse and Physician of Patient #1's pretreatment blood</p>	V 504			

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V 504	<p>Continued From page 41 pressure.</p> <p>The Flowsheet dated 8/18/2023 documented Patient #1's pretreatment sitting BP, was 180/92. The agency failed to follow policies and procedures and failed to notify the Nurse and Physician of Patient #1's pretreatment blood pressure.</p> <p>The flowsheet dated 8/21/2023 documented Patient #1's pretreatment HR 110 and irregular. The agency failed to follow policies and procedures and failed to notify the Nurse and Physician of Patient #1's pretreatment heart rate.</p> <p>7. Clinical record review on 8/24/2023 for Patient #2, start of care 2/7/2023, included a review of the dialysis treatment sheets from 7/25/2023 through 8/19/2023 and evidenced the following:</p> <p>The Flowsheet dated 7/25/2023 documented Patient #2's BP at 2:38 PM, was 80/42, BP was retaken and was 115/44; at 3:00 PM, BP was 100/50 and at 3:32 PM, BP was 96/53; at 4:06 PM, BP was 104/46; at 4:36 PM, BP was 104/41; and at 5:09 PM, BP was 114/51. The agency failed to follow policies and procedures and failed to notify the Nurse and Physician of Patient #2's low blood pressure.</p> <p>The Flowsheet dated 7/27/2023 documented Patient #2's BP at 2:30 PM, was 93/51; at 3:01 PM, BP was 101/50. The agency failed to follow policies and procedures and failed to notify the Nurse and Physician of Patient #2's low blood pressure.</p> <p>The Flowsheet dated 7/29/2023 documented Patient #2's pretreatment sitting BP, was 192/76;</p>	V 504			

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V 504	<p>Continued From page 42</p> <p>at 3:33 PM, BP was 99/40; at 4:01 PM, BP was 101/48; and at 4:31 PM, BP was 97/53. The agency failed to follow policies and procedures and failed to notify the Nurse and Physician of Patient #2's blood pressure.</p> <p>The Flowsheet dated 8/3/2023 documented Patient #2's pretreatment sitting BP, was 216/97; at 1:02 PM, BP was 257/116; at 1:03 PM, BP was 192/78; and at 1:32 PM, BP was 204/91. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #2's blood pressure.</p> <p>The Flowsheet dated 8/5/2023 documented Patient #2's pretreatment sitting BP, was 156/112, HR was 129; at 2:03 PM, BP was 123/63; and at 2:31 PM, BP was 114/47. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #2's blood pressure.</p> <p>The Flowsheet dated 8/8/2023 documented Patient #2's BP at 4:31 PM, was 96/52; at 4:38 PM, BP was 88/40. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #2's blood pressure.</p> <p>The Flowsheet dated 8/12/2023 documented Patient #2's BP at 3:04 PM, was 93/27; at 3:32 PM, BP was 93/65; and at 4:53 PM, BP was 152/126. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #2's blood pressure.</p> <p>The Flowsheet dated 8/17/2023 documented Patient #2's BP post-treatment was 188/84. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #2's blood pressure.</p>	V 504		

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V 504	Continued From page 43 The Flowsheet dated 8/19/2023 documented Patient #2's BP pretreatment was 117/33; at 2:05 PM, BP was 80/46; at 2:06 PM, BP was 98/53; and at 2:30 PM, BP was 120/62. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #2's blood pressure. 8. Clinical record review on 8/24/2023 for Patient #3, start of care 5/16/2019, included a review of the dialysis treatment sheets from 7/28/2023 through 8/21/2023 and evidenced the following: The Flowsheet dated 8/3/2023 documented Patient #3's BP at 1:35 PM, was 153/101; at 2:03 PM, BP was 180/60; at 2:05 PM, BP was 180/59; and at 3:16 PM, BP was 182/85. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #3's blood pressure. The Flowsheet dated 8/4/2023 documented Patient #3's BP at 2:35 PM, was 190/79; at 1:40 PM, BP was 133/100; and at 2:37 PM, BP was 143/59. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #3's blood pressure. The Flowsheet dated 8/9/2023 documented Patient #3's BP at 1:00 PM, was 192/97. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #3's blood pressure. The Flowsheet dated 8/14/2023 documented Patient #3's BP at 12:31 PM, was 180/74; and at 2:04 PM, BP was 114/46. The agency failed to follow policies and procedures and failed to notify	V 504			

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V 504	Continued From page 44 the Physician of Patient #3's blood pressure. The Flowsheet dated 8/18/2023 documented Patient #3's BP at 12:31 PM, was 183/75; at 2:33 PM, BP was 185/78; and at 3:09 PM, BP was 196/101. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #3's blood pressure. The Flowsheet dated 8/18/2023 documented Patient #3's BP at 12:22 PM, was 188/95; at 3:01 PM, BP was 184/53; at 3:10 PM, BP was 187/81; and post-treatment BP was 188/65. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #3 blood pressure. 9. Clinical record review on 8/24/2023 for Patient #4, start of care 2/1/2022, included a review of the dialysis treatment sheets from 5/4/2023 through 5/30/2023 and evidenced the following: The Flowsheet dated 5/18/2023 documented Patient #4's BP at 8:18 AM, was 58/25 and HR 44 treatment was initiated at 8:18 AM; at 8:33 AM, BP was 144/59. The agency failed to follow policies and procedures and failed to notify the Physician of Patient #4's blood pressure. During an interview on 8/29/2023 at 12:41 PM, the Facility Administrator indicated any systolic BP over 180 or under 100 should be reported to the Nurse. She indicated if the blood pressure is abnormal for the patient, then it should be reported.	V 504			
V 516	PA-FREQUENCY-INITIAL-30 DAYS/13 TX CFR(s): 494.80(b)(1)	V 516			

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V 516	Continued From page 45 An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session. This STANDARD is not met as evidenced by: Based on record review and interview, the dialysis facility failed to ensure an initial comprehensive assessment was conducted within 30 calendar days or within 13 hemodialysis sessions for 1 of 1 clinical record reviewed for a patient recently transferred (admitted) to the facility (Patient #7). The findings include: Record review for Patient #7 (admit date 6/19/2023) evidenced the patient recently transferred from a facility in another state. The clinical record failed to evidence that an initial comprehensive assessment was conducted within 30 calendar days or within 13 hemodialysis sessions since admission. The clinical record failed to evidence that a comprehensive assessment from Entity 1 (out of state dialysis facility) was received. During an interview on 8/25/2023 at 2:38 PM, the Regional Social Work Manager (corporate) indicated they were out of compliance, and comprehensive assessments weren't completed.	V 516			
V 520	PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO CFR(s): 494.80(d)(2) In accordance with the standards specified in	V 520			

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V 520	<p>Continued From page 46</p> <p>paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted-</p> <p>At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the dialysis facility failed to ensure a comprehensive reassessment of the patient occurred and/or a revision of the plan of care was made to meet the patient's needs for 2 of 2 records reviewed with unstable patients (Patient #5, 7).</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Review of an undated document received on 8/22/2023, titled "Unstable Patients", evidenced Patient #5 was listed as unstable in May, June, and July, 2023, but failed to evidence Patient #7 was unstable. 2. Record review for patient #5 evidenced a physician's progress note, which evidenced on 5/18/2023, the patient's Erythropoiesis-Stimulating Agents (ESA) (to treat anemia, or low red blood cell count) therapy was discontinued due to hemoglobin (Hgb) level at 13.3. 	V 520			

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V 520	<p>Continued From page 47</p> <p>Review of a Social Worker (SW) comprehensive assessment dated 7/10/2023, evidenced the patient moved to the area to be with family after sustaining a stroke (2010) which left her debilitated on her left side, and she required total care.</p> <p>Review of Registered Nurse (RN) comprehensive assessments dated 6/10/2023 and 7/10/2023, evidenced the patient had no pain.</p> <p>Review of an undated document titled "Lab Results" evidenced the patient's hemoglobin (Hgb) level was 14.6 (normal range for females is 12-15.2) on 6/13/2023, and 12.9 on 7/11/2023.</p> <p>Review of plans of care dated 6/13/2023, and 7/11/2023 both evidenced interventions to refer to Physical Therapy (PT), and an intervention to change ESA dose; evidenced Hgb goal was 10-11, and a goal for patient to verbalize decreased pain levels; but failed to evidence the plans of care were revised to reflect the patient's physical status, the patient's Hgb was sustained and above the target goal, the patient no longer took ESAs, or the patient had no pain.</p> <p>During an interview on 8/24/2023 at 3:27 PM, the Charge Nurse indicated she didn't know if the patient ever received physical therapy, and the Dietician indicated the patient received services at home from Entity 4 (an organization that provides comprehensive medical and social services to frail, elderly people).</p> <p>3. Record review for Patient #7 (admit date 6/19/2023) evidenced a nutrition progress note</p>	V 520			

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V 520	<p>Continued From page 48</p> <p>dated 7/12/2023 indicated the patient recently transferred to the facility from another state, and wasn't meeting the nutritional goals.</p> <p>Review failed to evidence presence of any comprehensive assessments or reassessments, or any plans of care.</p> <p>Review of treatment sheets from 7/17/2023 - 8/21/2023 evidenced the patient continually declined in health status, went from the ability to walk to non-ambulatory, had consistent hypotension (low blood pressure), and developed lower extremity edema (swelling caused by excessive fluid build up).</p> <p>Review of a document received from Entity 3 (a hospital) dated 8/22/2023, evidenced the patient was seen in the Emergency Department (ED) on 8/22/2023, family reported the patient had been having increased weakness, worsening mobility, and was no longer able to walk; the patient fell this morning while attempting to stand up and transfer to his electric scooter, sustained a traumatic fracture, and subsequently passed away in the ED that day (8/22/2023).</p> <p>During an interview on 8/25/2023 at 11:40 AM, the Facility Administrator (FA) indicated there were no treatment notes 8/23/2023 to present, because the patient died Wednesday (8/23/2023).</p> <p>During an interview on 8/25/2023 at 2:38 PM, the Regional Social Work Manager (corporate) indicated they were out of compliance with the plan of care, should have completed comprehensive assessments, and created a plan of care. The Dietician indicated the patient should</p>	V 520			

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
V 520	Continued From page 49 have been listed as unstable, due to his condition. The Charge Nurse indicated the patient moved up here to be with family because he had declined so much, and he would have probably benefited from hospice services. During an interview on 8/25/2023 at 3:08 PM, Person 1 (staff at Entity 1, an assisted living facility [ALF]) indicated Patient #7 stood up, and because of weakness, fell directly to the ground, sustained a compound fracture (an open wound or break in the skin near the site of the broken bone), she believed it was his left lower leg, he's been on dialysis, last Friday (8/18/2023) he said he was giving up, and didn't know if he wanted to continue. Person 1 also indicated the patient passed away while at the hospital.	V 520			
V 540	CFC-PATIENT PLAN OF CARE CFR(s): 494.90 This CONDITION is not met as evidenced by: Based on observation, record review, and interview the dialysis center failed to ensure the patient's plan of care was individualized, and/or included measurable interventions, outcomes, or goals (V541), failed to ensure a plans of care were developed for all patients (V542), failed to notify the Physician of patients' dry weights and failed to monitor and assess patients per policy (V543), failed to ensure prescriptions were verified and adhered to (V544), failed to provide the necessary care for patients to achieve appropriate albumin levels (V545), failed to provide the necessary care for patients to manage minreal metabolism (V546), failed to provide necessary care and services to achieve	V 540			

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V 540	Continued From page 50 appropriate hemoglobin levels (V547), failed to ensure patient access sites were washed prior to treatment (V550), and failed to ensure patients' access sites were monitored for symptoms of stenosis (V551), failed to ensure the patient received the necessary services to meet psychosocial needs (552), failed to adjust the patient's plan of care the achieve the expected goals (V559).	V 540			
V 541	POC-GOALS=COMMUNITY-BASED STANDARDS CFR(s): 494.90 The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards. This STANDARD is not met as evidenced by: Based on record review and interview, the interdisciplinary team (IDT) failed to ensure the patient's plan of care was individualized, and/or	V 541			

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V 541	<p>Continued From page 51</p> <p>included measurable interventions, outcomes, or goals, for 4 of 7 records reviewed (Patient #1, #2, #3, #4).</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Review of an agency policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care, Published 7/3/2023, stated, " ... The plan of care must include measurable and expected outcomes and an estimated timetable to achieve these outcomes...." 2. Record review for Patient #1 evidenced a plan of care dated 11/22/2022, which evidenced the Patient had an area of focus for Change in mental status an entry documented within the goal by Registered Nurse (RN) 4, dated 11/16/2023, indicated the goal was to identify the cause and provide treatment, but failed to indicate what the treatment was, and the interventions were to address symptoms but failed to include what the symptoms where and what was being done to address them. <p>The plan of care evidenced an area of focus for Diabetes Management documented 11/16/2022, which indicated the Patient's A1C results would be in normal range or as specified by the Physician, the intervention included to add, adjust, or discontinue diabetes medications. This area of focus failed to be individualized for the patient.</p> <p>The plan of care evidenced an area of focus for Blood Pressure (BP) and fluid management, with a goal to achieve BP control as specified by the patient's physician but failed to evidence what the physician specified; the intervention included to</p>	V 541			

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V 541	<p>Continued From page 52</p> <p>add, adjust, and to discontinue BP medications. This area of focus failed to be individualized for the patient.</p> <p>The plan of care evidenced an area of focus for treatment adherence which indicated a goal to improve treatment adherence and the intervention to identify barriers leading to missed/shortened treatments. This focus indicated the patient was adherent to his treatment and there were no concerns. Documentation showed the patient is scheduled three times a week and only comes twice per week, no barriers were identified to improve the treatment adherence.</p> <p>The plan of care evidenced an area of focus for ability to independently function, with a goal to achieve and maintain optimal level of independent function (ability to perform activities of daily living, such as bathing, dressing, toileting), but failed to evidence the patient's current level of function or a patient-specific goal.</p> <p>3. Record review for Patient #2 evidenced a plan of care dated 4/13/2023, which evidenced the Patient had an area of focus for Change in mental status an entry documented within the goal by Registered Nurse (RN) 4, dated 11/16/2023, indicated the goal was to identify the cause and provide treatment, but failed to indicate what the treatment was, and the interventions were to address symptoms but failed to include what the symptoms where and what was being done to address them.</p> <p>The plan of care evidenced an area of focus for Diabetes Management documented 4/12/2023, which indicated the Patient's A1C results would</p>	V 541			

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V 541	<p>Continued From page 53</p> <p>be in normal range or as specified by the Physician but failed to indicate what the range or specification would be</p> <p>The plan of care evidenced an area of focus for ability to independently function, with a goal to achieve and maintain optimal level of independent function (ability to perform activities of daily living, such as bathing, dressing, toileting), but failed to evidence the patient's current level of function or a patient-specific goal.</p> <p>4. Record review for Patient #3 evidenced a plan of care dated 6/16/2023, which evidenced the Patient had an area of focus for Anemia Management, the goal was to have her hemoglobin between 10-11 but failed to indicate what her hemoglobin was, intervention to monitor hemoglobin. The intervention anemia management failed to be individualized for patient #3.</p> <p>5. Record review for Patient #4 evidenced a plan of care dated 6/28/22, which evidenced an area of focus for Blood Pressure (BP) and fluid management, with a goal to achieve BP control as specified by the patient's physician but failed to evidence what the physician specified; and the intervention included to add, adjust to discontinue BP medications. This area of focus failed to be individualized for the patient.</p> <p>The plan of care evidenced an area of focus for hospitalization within the last 90 days, with a goal for the patient to not be hospitalized but failed to evidence the individualized root cause of the hospitalization(s), or interventions to prevent further hospitalizations.</p>	V 541			

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V 541	Continued From page 54	V 541			
V 542	<p>During an interview on 8/27/2023 at 2:51 PM, the Director of Operations indicated the plans of care are a focus, and we are in the process of making the paperwork better. We do so much, but it is not reflected in the documentation. He indicated the system makes it hard to individualize.</p> <p>POC-IDT DEVELOPS PLAN OF CARE CFR(s): 494.90(a)</p> <p>The interdisciplinary team must develop a plan of care for each patient.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the interdisciplinary team (IDT) failed to ensure it developed a plan of care (POC) for 1 of 1 clinical record reviewed with a recent admit date (Patient #7).</p> <p>The findings include:</p> <p>Record review for Patient #7 (admit date 6/19/2023) failed to evidence a POC was developed by the IDT.</p> <p>A plan of care (dated 12/14/202) from the patient's previous dialysis facility (Entity 1), evidenced Entity 1's POC wasn't received by the facility until 8/25/2023 at 1:55 PM.</p> <p>During an interview on 8/25/2023 at 11:40 AM, the Facility Administrator (FA) indicated they didn't have a POC for the patient because they had 90 days to do one, they didn't receive a plan of care from Entity 1, but she would call them and have them fax one.</p> <p>During an interview on 8/25/2023 at 2:38 PM, the</p>	V 542			

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V 542	Continued From page 55 Regional Social Work Manager (corporate) indicated they were out of compliance with the POC, and they should have had IDT meetings and created a POC.	V 542			
V 543	POC-MANAGE VOLUME STATUS CFR(s): 494.90(a)(1) The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; This STANDARD is not met as evidenced by: Based on observation, record review, and interview the facility failed to ensure the physician was aware of patients below their dry weight prior to treatment, the inability of the patient to achieve their dry weight to establish the appropriateness of the dialysis prescriptions, and failed to notify the physician when post-treatment weight was greater than/less than 1 kilogram of the ordered dry weight for 4 of 7 hemodialysis records reviewed (Patient #1, #2, #3, #4) and failed to ensure patients were assessed and/or monitored per policy in 5 of 7 hemodialysis patients clinical records reviewed. (Patient #1, #2, #3, #4.#5) The findings include: 1. An agency policy titled "Volume Management in ESRD [End Stage Renal Disease] Patients on Hemodialysis" published 9/7/2021 stated "If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with the physician for appropriate fluid interventions:... Pre-treatment weight is less than or equal to EDW EDW order should be	V 543			

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V 543	<p>Continued From page 56</p> <p>updated post-treatment adjustments and patient fluid status ... the clinical care team must be diligent in determining the EDW and routinely assess and adjust this metric ... EDW order should be updated post-treatment to reflect treatment adjustments and patient fluid status ... The assessment of EDW remains a clinical judgment of a clinical judgment of a clinician and clinical care team ... Obtain blood pressure and pulse at least every 30 minutes or more often as needed "</p> <p>2. An agency policy titled "Patient Assessment and Monitoring" published 5/1/2023 stated, "If the PCT/LPN notes any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or if the patient was hospitalized, the patient care technician MUST report the changes to a registered nurse Any abnormal finding confirmed by the RN [registered nurse] will be reported to the attending physician ... Maintain the patient post-treatment weight and ensure the post weight is consistent with the goal set of the machine ... Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes per state regulations ... The Registered Nurse will assess/reassess post-treatment as indicated"</p> <p>3. An agency policy titled "Nursing Supervision and Delegation," published 5/1/2023, stated, " ... the following task may not be delegated: assessment of each patient preferably within one hour (or according to state requirements) of treatment initiation in the clinic setting...."</p> <p>4. Clinical record review on 8/24/2023 for Patient #1, start of care 8/19/2022, included a review of</p>	V 543			

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V 543	<p>Continued From page 57</p> <p>the dialysis treatment sheets from 7/26/2023 through 8/21/2023 and evidenced the following:</p> <p>The Flowsheets dated 7/28/2023, 7/31/2023, 8/4/2023, 8/7/2023, 8/11/2023, 8/18/2023, and 8/21/2023 failed to evidence Patient #1 was assessed by the Nurse post-treatment.</p> <p>The flowsheet dated 7/28/2023, documented Patient #1's Estimated dry weight (EDW) was 74.5 kilograms (kg), his pretreatment weight was 74.2 kg, and his post-treatment weight was 73.6 kg. The agency failed to notify the Physician the Patient was under his dry weight.</p> <p>The flowsheet dated 7/31/2023 documented Patient #1's EDW was 74.5 kg, his pretreatment weight was 74.4 kg, and his post-treatment weight was 73.5 kg. The agency failed to notify the Physician the Patient was under his dry weight.</p> <p>The flowsheet dated 8/7/2023 documented Patient #1's EDW was 74.5 kg, and his post-treatment weight was 73.2 kg. The agency failed to notify the Physician the Patient was under his dry weight.</p> <p>The flowsheet dated 8/11/2023 documented Patient #1's EDW was 74.5 kg, his pretreatment weight was 73.5 kg, and his post-treatment weight was 73 kg. The agency failed to notify the Physician the Patient was under his dry weight.</p> <p>The flowsheet dated 8/18/2023 documented Patient #1's EDW was 74.5 kg, his pretreatment weight was 74.2 kg, and his post-treatment weight was 73 kg. The agency failed to notify the Physician the Patient was under his dry weight.</p>	V 543			

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V 543	<p>Continued From page 58</p> <p>The flowsheet dated 8/18/2023 documented Patient #1's EDW was 74.5 kg, his pretreatment weight was 73.4 kg, and his post-treatment weight was 72.10 kg. The agency failed to notify the Physician the Patient was under his dry weight.</p> <p>During an interview on 8/29/2023 at 11:11 AM, the Facility Administrator thanked the Surveyor for bringing Patient #1's weight to her attention and indicated she changed his dry weight in the computer.</p> <p>5. Clinical record review on 8/24/2023 for Patient #2, start of care 2/7/2023, included a review of the dialysis treatment sheets from 7/25/2023 through 8/19/2023 and evidenced the following:</p> <p>The flowsheet dated 7/25/2023 evidenced Patient #2's EDW was 113 kg; her pre-weight was 120.3 kg, and her post-weight was 115.2 kg. The agency failed to notify the Physician the Patient did not meet her dry weight.</p> <p>The Flowsheets dated 7/25/2023, 7/27/2023, 7/29/2023, 8//2023, 8/11/2023, 8/18/2023, and 8/21/2023 failed to evidence Patient #2 was assessed by the Nurse post-treatment.</p> <p>The flowsheet dated 7/27/2023 evidenced Patient #2's EDW was 113 kg; her pre-weight was 120.2 kg, and her post-weight was 118 kg. The agency failed to notify the Physician the Patient did not meet her dry weight.</p> <p>The flowsheet dated 7/29/2023 evidenced Patient #2's EDW was 116 kg; her pre-weight was 120.3 kg, and her post-weight was 117.5 kg. The</p>	V 543			

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V 543	<p>Continued From page 59</p> <p>agency failed to notify the Physician the Patient did not meet dry weight.</p> <p>The flowsheet dated 8/1/2023 failed to evidence a preassessment was completed by the Registered Nurse.</p> <p>The flowsheet dated 8/5/2023 failed to evidence a complete preassessment was completed by the Registered Nurse The flowsheet documented Patient #2's BP was monitored at 2:31 PM and not again until 3:50 PM. The agency failed to monitor Patient #2 every 30 minutes.</p> <p>The flowsheet dated 8/8/2023 evidenced Patient #2's EDW was 116 kg; her pre-weight was 119.7 kg, and her post-weight was 117.3 kg. The agency failed to notify the Physician the Patient did not meet her dry weight.</p> <p>The flowsheet dated 8/10/2023 failed to evidence a post-assessment was completed by the Registered Nurse The flowsheet documented Patient #2's BP was monitored at 4:02 PM and not again until 4:52 PM. The agency failed to monitor Patient #2 every 30 minutes.</p> <p>The flowsheet dated 8/12/2023 evidenced Patient #2's EDW was 116 kg; her pre-weight was 119.4 kg, and her post-weight was 117.5 kg. The flowsheet documented Patient #2's BP was monitored at 4:03 PM and not again until 4:53 PM. The agency failed to monitor Patient #2 every 30 minutes. The agency failed to notify the Physician the Patient did not meet her dry weight, and the agency failed to monitor Patient #2 every 30 minutes.</p> <p>The flowsheet dated 8/15/2023 evidenced Patient</p>	V 543			

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V 543	<p>Continued From page 60</p> <p>#2's EDW was 116 kg; her pre-weight was 122.8 kg, and her post-weight was 120.5 kg. The agency failed to notify the Physician the Patient did not meet her dry weight.</p> <p>The flowsheet dated 8/17/2023 evidenced Patient #2's EDW was 116 kg; her pre-weight was 120.3 kg, and her post-weight was 117.7 kg. The agency failed to notify the Physician the Patient did not meet her dry weight.</p> <p>The flowsheet dated 8/19/2023 evidenced Patient #2's EDW was 116 kg; her pre-weight was 120.8 kg, and her post-weight was 119.3 kg. The agency failed to notify the Physician the Patient did not meet her dry weight.</p> <p>6. Clinical record review on 8/24/2023 for Patient #3, start of care 5/16/2019, included a review of the dialysis treatment sheets from 7/28/2023 through 8/21/2023 and evidenced the following:</p> <p>The flowsheet dated 7/26/2023 evidenced Patient #3's EDW was 111.5 kg and her post-weight was 112.6 kg. The flowsheet also failed to evidence a post-assessment was completed by the Registered Nurse. The agency failed to notify the Physician the Patient did not meet her dry weight and failed to assess the patient after treatment.</p> <p>The flowsheet dated 7/31/2023, 8/11/2023, 8/14/2023, 8/18/2023, and 8/21/2023 failed to evidence a post-treatment assessment was completed by the Registered Nurse.</p> <p>The flowsheet dated 8/9/2023 failed to evidence a post-treatment assessment was completed by the Registered Nurse The flowsheet documented Patient #3's BP was monitored at 12:06 PM and</p>	V 543			

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V 543	<p>Continued From page 61 not again until 1:05 PM. The agency failed to monitor Patient #3 every 30 minutes.</p> <p>The flowsheet dated 8/11/2023 evidenced Patient #3's EDW was 111.5 kg, and her post weight was 110.5 kg. The agency failed to notify the Physician the Patient did not meet her dry weight.</p> <p>7. Clinical record review on 8/24/2023 for Patient #4, start of care 2/1/2022, included a review of the dialysis treatment sheets from 5/4/2023 through 5/30/2023 and evidenced the following:</p> <p>The flowsheet dated 5/4/2023 evidenced Patient #4's treatment started at 8:13 AM, the RN failed to document a pretreatment assessment until 9:24 AM, the flowsheet failed to evidence a post-treatment assessment was completed by the Registered Nurse documentation evidenced Patient #4's BP was monitored at 10:20 AM and not again until 11:32 AM. failed to ensure the Patient was assessed by the RN within an hour of the treatment start time, failed to monitor Patient #3 every 30 minutes, and failed to ensure a post assessment was done by the RN.</p> <p>The flowsheet dated 5/6/2023 evidenced Patient #4's treatment started at 7:53 AM, the RN failed to document a pretreatment assessment until 11:38 AM, the flowsheet failed to evidence a post-treatment assessment was completed by the RN, documentation evidenced Patient #4's BP was monitored at 10:20 AM and not again until 11:32 AM and failed to ensure the Patient was assessed by the RN within an hour of the treatment start time.</p> <p>The flowsheet dated 5/9/2023 evidenced Patient #4' BP was monitored at 11:14 PM, treatment</p>	V 543			

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V 543	<p>Continued From page 62</p> <p>ended at 12:17 PM, and there was no evidence of another BP monitoring until after the treatment ended. The documentation failed to evidence the RN performed a post-assessment and failed to evidence the BP was monitored every 30 minutes.</p> <p>The flowsheet dated 5/16/2023 evidenced Patient #4's EDW was 85 kg and his post-weight was 86 kg. The agency failed to notify the Physician the Patient did not meet his dry weight.</p> <p>The flowsheet dated 5/18/2023 evidenced Patient #4's treatment started at 8:18 AM, the RN failed to document a pretreatment assessment until 10:01 AM, documentation failed to evidence the RN completed a post-treatment assessment. The agency failed to ensure the Patient was assessed by the RN within an hour of the treatment start time.</p> <p>The flowsheet dated 5/20/2023 evidenced Patient #4's EDW was 85 kg; his pre-weight and his post-weight was 86.8 kg. Documentation failed to evidence the RN completed a post-treatment assessment. The agency failed to notify the Physician the Patient did not meet his dry weight.</p> <p>The flowsheet dated 5/23/2023 evidenced Patient #4's EDW was 85 kg; his pre-weight and his post-weight was 88 kg. Documentation failed to evidence the RN completed a post-treatment assessment. The agency failed to notify the Physician the Patient did not meet his dry weight.</p> <p>The flowsheet dated 5/25/2023 evidenced Patient #4's EDW was 85 kg; his pre-weight and his post-weight was 86.2 kg. Documentation failed to evidence the RN completed a post-treatment</p>	V 543			

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V 543	<p>Continued From page 63</p> <p>assessment. The agency failed to notify the Physician the Patient did not meet his dry weight.</p> <p>The flowsheet dated 5/27/2023 evidenced Patient #4's EDW was 85 kg; his pre-weight and his post-weight was 86.6 kg. Documentation failed to evidence the RN completed a post-treatment assessment. The agency failed to notify the Physician the Patient did not meet his dry weight.</p> <p>The flowsheet dated 5/30/2023 evidenced Patient #4's EDW was 85 kg; his pre-weight and his post-weight was 87.5 kg. Documentation failed to evidence the RN completed a post-treatment assessment. The agency failed to notify the Physician the Patient did not meet his dry weight.</p> <p>During an interview on 8/29/2023 at 12:50 PM, the FA indicated a post-assessment should be done by the Nurse after every treatment, she indicated pre-assessments should be done within the first hour of treatment.</p> <p>During an interview on 8/29/2023 at 3:14 PM, the FA indicated weights are checked weekly to see if they need to be adjusted.</p> <p>8. Record review for patient #5 (admit date 5/26/2020) evidenced a treatment sheet dated 7/25/2023, which failed to evidence a post-dialysis assessment was completed by a RN.</p> <p>A treatment sheet dated 7/25/2023, 8/10/2023 failed to evidence a post-dialysis assessment was completed by a RN, and the patient's post-treatment EDW was 1.1 kg below target EDW (76.0 kg).</p> <p>Treatment sheets dated 7/29/2023, 8/01/2023,</p>	V 543			

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V 543	Continued From page 64 8/12/2023 failed to evidence neither a pre nor post-dialysis assessment was completed by a RN. Treatment sheets dated 8/03/2023, 8/05/2023, 8/08/2023, 8/17/2023, and 8/19/2023 , failed to evidence a post-dialysis assessment was completed by a RN. A treatment sheet dated 8/15/2023 failed to evidence a pre-dialysis assessment was completed by a RN. 9 During an interview on 8/24/2023 at 3:15 PM, the Facility Administrator (FA) indicated the RN assessed the patients before and after dialysis treatments, and with any reported or observed issues during treatment, assessments included checking for edema, neurological status, lung sounds, and something abnormal; and the Director of Operations indicated there was a basic assessment that would pull over to the treatment sheet if it was done.	V 543			
V 544	POC-ACHIEVE ADEQUATE CLEARANCE CFR(s): 494.90(a)(1) Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the facility failed to ensure patient dialysis prescriptions orders were verified and	V 544			

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V 544	<p>Continued From page 65</p> <p>adhered to in order to achieve and sustain the prescribed dose of dialysis to meet the adequacy of dialysis in 6 out of 7 hemodialysis records reviewed (Patient #1, #2, #3, #4, #5, #6)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. An agency policy titled "Patient Assessment and Monitoring, " published 5/1/2023, stated " ... Check the machine settings and measurements, check the prescribed blood flow is being achieved or reason is documented in the medical record if unable to meet the prescribed flow rate. Check dialysate flow rate setting is correct the prescribed flow is being delivered...." 2. Clinical record review on 8/24/2023 for Patient #1, start of care 8/19/2022, included a review of the dialysis treatment sheets from 7/27/2023 through 8/19/2023 and evidenced the following: The flowsheet dated 8/18/2023 documented Patient #1's prescribed blood flow rate (BFR) was 400 ml/min, at 12:34 PM, the BFR was changed to 500 ml/min until 1:01 PM. 3. Clinical record review on 8/24/2023 for Patient #2, start of care 2/7/2023, included a review of the dialysis treatment sheets from 7/25/2023 through 8/19/2023 and evidenced the following: The flowsheet dated 7/25/2023 documented Patient #2's prescribed BFR was 500 ml/min, at 2:38 PM, the BFR was changed to 440 ml/min until 1:01 PM. This flowsheet indicated the patient was to receive 4 hours of treatment and only received 3 hours and 48 minutes. This document failed to evidence why Patient #2 did not get her prescribed treatment. 	V 544			

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V 544	Continued From page 66 The flowsheet dated 7/27/2023 documented Patient #2's prescribed BFR was 500 ml/min and dialysate flow rate (DFR) was 800ml/min. During treatment, the patient's DFR was 500 ml/min, and at 3:02 PM, the BFR was changed to 450 ml/min. This document failed to evidence why Patient #2 did not get her prescribed treatment. The flowsheet dated 7/29/2023 documented Patient #2's prescribed BFR was 500 ml/min and DFR was 800 ml/min. During treatment, the patient's BFR was 450 ml/min and DFR was 500 ml/min. This flowsheet indicated the patient was to receive 4 hours of treatment and only received 3 hours and 18 minutes. This document failed to evidence why Patient #2 did not get her prescribed treatment. The flowsheet dated 8/1/2023 documented Patient #2's prescribed BFR was 500 ml/min and DFR was 800 ml/min. During treatment, the patient's BFR was 400 ml/min and DFR was 500 ml/min. This flowsheet indicated the patient was to receive 4 hours of treatment and only received 3 hours and 45 minutes. This document failed to evidence why Patient #2 did not get her prescribed treatment. The flowsheet dated 8/3/2023 documented Patient #2 was to receive 4 hours of treatment and only received 3 hours and 22 minutes. This document failed to evidence why Patient #2 did not get her prescribed treatment. The flowsheet dated 8/5/2023 documented Patient #2's prescribed DFR was 800 ml/min. During treatment, Patient #2's DFR was reduced to 500 ml/min. This flowsheet indicated the	V 544			

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V 544	<p>Continued From page 67</p> <p>patient was to receive 4 hours of treatment and only received 3 hours and 36 minutes. This document failed to evidence why Patient #2 did not get her prescribed treatment.</p> <p>The flowsheet dated 8/8/2023 documented Patient #2's prescribed BFR was 500 ml/min. During treatment, the patient's BFR was 430 ml/min. This document failed to evidence why Patient #2 did not get her prescribed treatment.</p> <p>The flowsheets dated 8/10/2023 and 8/14/2023 documented Patient #2's prescribed BFR was 500 ml/min. During treatments, the patient's BFR was 450 ml/min. These documents failed to evidence why Patient #2 did not get her prescribed treatment.</p> <p>The flowsheet dated 8/12/2023 documented Patient #2's prescribed BFR was 800 ml/min. During treatment, Patient #2's BFR was 450 ml/min, then reduced to 385 ml/min at 2:01 PM, and reduced to 300 ml/min at 4:53 PM. This flowsheet indicated the patient was to receive 4 hours of treatment and only received 3 hours and 39 minutes. This document failed to evidence why Patient #2 did not get her prescribed treatment.</p> <p>The flowsheet dated 8/12/2023 documented Patient #2's prescribed BFR was 800 ml/min. During treatment, Patient #2's BFR was 450 ml/min at 3:06 PM and was reduced to 400 ml/min at 5:02 PM. This document failed to evidence why Patient #2 did not get her prescribed treatment.</p> <p>The flowsheets dated 8/19/2023 and 8/14/2023 documented Patient #2's prescribed BFR was</p>	V 544			

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V 544	<p>Continued From page 68</p> <p>500 ml/min. During treatments, the patient's BFR was 450 ml/min. These documents failed to evidence why Patient #2 did not get her prescribed treatment.</p> <p>4. Clinical record review on 8/24/2023 for Patient #3, start of care 5/16/2019, included a review of the dialysis treatment sheets from 7/28/2023 through 8/21/2023 and evidenced the following:</p> <p>The flowsheet dated 7/28/2023 documented Patient #3's prescribed BFR was 500 ml/min. During treatments, the patient's BFR was reduced to 400 ml/min. This flowsheet indicated the patient was to receive 3.5 hours of treatment and only received 2 hours and 42 minutes. The document failed to evidence why Patient #3 did not get her prescribed treatment.</p> <p>The flowsheet dated 8/4/2023 documented Patient #3's prescribed BFR was 500 ml/min. During treatment, the patient's BFR was reduced to 400 ml/min. The document failed to evidence why Patient #3 did not get her prescribed treatment.</p> <p>The flowsheet dated 8/14/2023 evidenced Patient #3 was to receive 3.5 hours of treatment and only received 3 hours and 20 minutes. This document failed to evidence the Physician was notified Patient #3 did not get her prescribed treatment.</p> <p>5. Clinical record review on 8/24/2023 for Patient #4, start of care 2/1/2022, included a review of the dialysis treatment sheets from 5/4/2023 through 5/30/2023 and evidenced the following:</p> <p>The flowsheet dated 5/13/2023 documented Patient #4's prescribed BFR was 500 ml/min.</p>	V 544			

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V 544	<p>Continued From page 69</p> <p>During treatment, the patient's BFR was 450 ml/min from 7:52 AM until 8:33 AM. The document failed to evidence why Patient #4 did not get her prescribed treatment.</p> <p>The flowsheet dated 5/27/2023 documented Patient #4's prescribed BFR was 500 ml/min. During treatment, the patient's BFR during treatment was 450 ml/min. The document failed to evidence why Patient #4 did not get her prescribed treatment.</p> <p>During an interview on 8/29/2023 at 3:15 PM, the FA indicated that if the BFR and/or DFR are not as prescribed, staff should have documented the reason for the change in the prescription.</p> <p>6. Record review for patient #5 (admit date 5/26/2020) evidenced treatment sheets dated July 25, 27, 29 (2023), and August 1, 5, 8, 10, 12, 15, 17, and 19 (2023), which all evidenced the patient's prescribed Blood Flow Rate (BFR) was 400, but the actual BFR provided was below the prescribed rate.</p> <p>7. Record review for Patient #6 (admit date 8/05/2022) evidenced a physician progress note, dated 7/07/2023, which evidenced the patient's prescribed BFR was 500; and a physician progress note dated 8/11/2023, which evidenced the patient's prescribed BFR was decreased to 300.</p> <p>Treatment sheets dated 7/26, 7/28, 7/31, 8/07, & 8/09 (2023) all evidenced the BFR was provided below the rate prescribed on 7/07/2023 (500).</p> <p>Treatment sheets dated 7/26 & 7/28, (2023) evidenced the dialysate flow rate (DFR) was 800,</p>	V 544			

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V 544	Continued From page 70 but DFR was provided at 500 for both treatments. A treatment sheet dated 7/28/2023 evidenced the prescribed treatment ended 21 minutes early per patient request, due to cramping. Record review evidenced treatments were missed on 8/02/2023 and 8/04/2023. A treatment sheet dated 8/11, 8/14, 8/16, & 8/18 (2023) evidenced the BFR was provided above the rate prescribed on 8/11/2023 (300). During an interview on 8/28/2023 at 1:37 PM, the Facility Administrator (FA) indicated the physician progress note dated 7/07/2023 did indicate the prescribed BFR was 500, the physician progress note dated 8/11/2023 indicated prescribed BFR was 300, but the BFR was 300; and the patient missed treatments on 8/02 & 8/04 (2023) was hospitalized for low hemoglobin. During an interview on 8/28/2023 at 2:39 PM, the Charge Nurse indicated any treatment shorter than 10-15 minutes of prescribed time would be considered a shortened end time, and the physician should be notified; and the Regional Social Work Manager (corporate) indicated a shortened treatment is any treatment shorter than the physician ordered.	V 544			
V 545	POC-EFFECTIVE NUTRITIONAL STATUS CFR(s): 494.90(a)(2) The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional	V 545			

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V 545	<p>Continued From page 71</p> <p>evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the dialysis center failed to provide the necessary care for patients to achieve appropriate albumin levels in 5 or 5 records reviewed of patients below goals. (Patients #2, #3, #4, #5, and #7)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. An agency policy titled Comprehensive Interdisciplinary Assessment and Plan of Care published 7/3/2023, stated, " ... If the patient-specific expected outcome as determined by the attending physician, IDT and patient for the plan of care is not achieved within the identified time frame the interdisciplinary team must adjust the patient 's plan of care and document changes made to the plan of care and implement the plan of care changes to address the identified issues" 2. Clinical record review for Patient #2, start of care 2/7/2023, evidenced plans of care dated 2/16/2023 and 4/13/2023. Both plans of care evidenced an area of focus was albumin management (the amount of protein in the blood), with a goal for albumin levels to be greater than or equal to 4.0, both indicated both documents Patient was not meeting her Albumin goal, and interventions for both indicated to "initiate/continue oral nutritional supplement per policy". <p>An undated document titled "Lab Results"</p>	V 545			

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V 545	<p>Continued From page 72</p> <p>evidenced the Patient # 2 had Albumin levels drawn on 6/6/2023, 7/4/2023, and 8/8/2023. Patient #2's Albumin level for all three blood draws were 3.7.</p> <p>3. Clinical record review for Patient #3 start of care 5/16/2019, evidenced plans of care dated 2/16/2023 and 4/13/2023. Both plans of care evidenced an area of focus was albumin management with a goal for albumin levels to be greater than or equal to 4.0, both indicated both documents Patient was not meeting his Albumin goal, and interventions were to monitor albumin and other nutrition-related labs monthly.</p> <p>An undated document titled "Lab Results" evidenced Patient # 3 had Albumin levels drawn on 8/11/2023- albumin was 2.9, 7/3/2023 albumin was 3.4 and 6/5/2023 albumin was 3.5.</p> <p>4. Clinical record review for Patient #4 start of care 2/1/2022, evidenced plans of care dated 2/16/2023 and 4/13/2023. Both plans of care evidenced an area of focus was albumin management with a goal for albumin levels to be greater than or equal to 4.0, both indicated both documents Patient was not meeting his Albumin goal.</p> <p>An undated document titled "Lab Results" evidenced Patient # 4 had Albumin levels drawn on 4/4/2023- albumin was 3.1, 3/23/2023 albumin was 3.3, 2/7/2233 albumin was 3.3 and 1/3/2023 albumin was 3.4.</p> <p>5. Record review for Patient #5 (admit date 5/26/2020) evidenced updated plans of care dated 6/13/2023 and 7/11/2023. Both plans of care evidenced an area of focus was albumin</p>	V 545			

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V 545	<p>Continued From page 73</p> <p>management (the amount of protein in your blood), with a goal for albumin levels to be greater than or equal to (>=) 4.0, both indicated the patient's albumin level was below goal, and interventions for both indicated to "initiate/continue oral nutritional supplement per policy".</p> <p>An undated document titled "Lab Results" evidenced the patient's albumin level was 3.1 on 6/06/2023, 3.2 on 7/04/2023, and 3.3 on 8/08/2023, all of which were below the target of 4.0.</p> <p>6. Record review for Patient #6 (admit date 8/05/2022) evidenced updated plans of care dated 11/22/2022 and 2/22/2023. Both plans of care evidenced an area of focus was albumin management, with a goal for albumin levels to be >= 4.0; the plan of care (POC) dated 11/22/2022 indicated the patient's albumin level was below goal, the POC dated 2/22/2023 indicated the patient's albumin goal was open, interventions were "in progress" as of 8/25/2022 , but no interventions were changed from the previous POC to achieve the albumin goal.</p> <p>An undated document titled "Lab Results" evidenced the patient's albumin level was 3.1 on 6/05/2023, 3.6 on 7/03/2023, and 3.0 on 8/07/2023, all of which were below the target of >= 4.0.</p> <p>During an interview on 8/28/2023 at 1:37 PM, the Dietician indicated she addressed the patient's mild malnutrition on POC by addressing protein (albumin levels) and other nutritional markers on the POC, they had an in-service on POCs in April, and indicated they clearly need to do it again.</p>	V 545			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152520	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 08/29/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA			STREET ADDRESS, CITY, STATE, ZIP CODE 710 PARK PL MISHAWAKA, IN 46545		
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V 545	Continued From page 74 7. Record review for Patient #7 (admit date 6/19/2023) evidenced an undated document titled "Lab Results", which evidenced the patient's albumin level was 3.8 on 6/19/2023, 3.6 on 7/03/2023, and 3.7 on 8/07/2023, all of which were below the target of 4.0, and failed to evidence a plan of care (POC) with interventions to mitigate the low albumin levels. During an interview on 8/25/2023 at 2:38 PM, the Regional Social Work Manager (corporate) indicated they were out of compliance with the POC, they should have had interdisciplinary team (IDT) meetings, and created a POC.	V 545			
V 546	POC-MANAGE MINERAL METABOLISM CFR(s): 494.90(a)(3) Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease. This STANDARD is not met as evidenced by: Based on record review and interview the dialysis center failed to provide the necessary care to manage phosphorus levels 1 of 1 clinical record reviewed for a patient recently transferred (admitted) to the facility (Patient #7). The findings include: 1. An agency policy titled Comprehensive Interdisciplinary Assessment and Plan of Care published 7/3/2023, stated, " ... If the patient-specific expected outcome as determined by the attending physician, IDT and patient for the plan of care is not achieved within the identified time frame the interdisciplinary team must adjust	V 546			

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V 546	Continued From page 75 the patient 's plan of care and document changes made to the plan of care and implement the plan of care changes to address the identified issues"	V 546			
V 547	<p>2. Record review for Patient #7 (admit date 6/19/2023) evidenced an undated document titled "Lab Results", which evidenced the patient's phosphorus level (target level is 3.5 - 5.5) was 3.2 on 6/19/2023, 1.8 on 7/03/2023, and 6.3 on 8/07/2023, all of which were either below or above the target level, and failed to evidence a plan of care (POC) with interventions to mitigate the abnormal phosphorus levels.</p> <p>During an interview on 8/25/2023 at 2:38 PM, the Regional Social Work Manager (corporate) indicated they were out of compliance with the POC, they should have had interdisciplinary team (IDT) meetings, and created a POC.</p> <p>POC-MANAGE ANEMIA/H/H MEASURED Q MO CFR(s): 494.90(a)(4)</p> <p>The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level.</p> <p>The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the dialysis center failed to provide the necessary</p>	V 547			

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V 547	<p>Continued From page 76</p> <p>care for patients to achieve appropriate hemoglobin level for 2 of 2 Patients not meeting anemia goals. (Patient #6, #7)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. An agency policy titled Comprehensive Interdisciplinary Assessment and Plan of Care published 7/3/2023, stated, " ... If the patient-specific expected outcome as determined by the attending physician, IDT and patient for the plan of care is not achieved within the identified time frame the interdisciplinary team must adjust the patient 's plan of care and document changes made to the plan of care and implement the plan of care changes to address the identified issues" 2. Record review for Patient #6 (admit date 8/05/2022) evidenced an updated plan of care (POC) 2/22/2023. The POC evidenced an area of focus was anemia management, with a goal for hemoglobin (Hgb) levels to be 10-11; the POC indicated the goal was open, ongoing, staff would monitor labs weekly and as needed, and change Erythropoiesis-Stimulating Agents (ESA) dose (to treat anemia), but no interventions were changed from the previous POC to achieve the Hgb goal. <p>A physician progress note dated 7/07/2023 evidenced dialysis treatment medication orders included Venofer 100 milligrams [mg] (an iron supplement to treat anemia) to be administered 3 times weekly, start date 7/07/2023 and end date 7/28/2023; and Mircera 225 micrograms [mcg] (an ESA) to be administered every 2 weeks.</p> <p>A treatment sheet dated 7/26/2023 indicated the last dose of Mircera (225 mcg) was last administered on 7/21/2023 (next dose due</p>	V 547			

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V 547	<p>Continued From page 77 8/04/2023); and Venofer 100 mg was administered.</p> <p>An undated document titled "Lab Results" evidenced the patient's hemoglobin Hgb level (normal range for males is 13.2 - 16.2) was tested weekly from 5/29/2023 - 7/24/2023, with a mean level of 8.23; and on 7/31/2023, the Hgb level was 6.3.</p> <p>Record review evidenced treatments were missed on 8/02/2023 and 8/04/2023.</p> <p>Treatment sheets dated 8/07/2023 and 8/09/2023 both indicated the last dose of Mircera was administered 7/21/2023, and no Venofer was administered.</p> <p>A physician progress note dated 8/11/2023 evidenced dialysis treatment medication orders included Venofer 100 mg to be given 3 times weekly, start date 8/09/2023 and end date 8/11/2023.</p> <p>A treatment sheet dated 8/11/2023 indicated the last dose of Mircera was administered 8/07/2023 (next dose due week of 8/20/2023), and Venofer was administered, and was still ordered 3 times weekly.</p> <p>Treatment sheets dated 8/14/2023, 8/16/2023, and 8/18/2023, and all failed to evidence Venofer was administered.</p> <p>A treatment sheet dated 8/21/2023 evidenced Venofer 50 mg was administered and ordered to be given weekly.</p> <p>A facility transfer report dated 8/23/2023</p>	V 547			

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V 547	Continued From page 78 evidenced Venofer wasn't ordered weekly until 8/18/2023. During an interview on 8/28/2023 at 1:37 PM, the Facility Administrator (FA) indicated the patient missed treatments on 8/02 & 8/04 (2023) because they sent the patient to the hospital on 8/02/2023 because his Hgb was low (6.3). The FA indicated the Mircera wasn't documented as given on the notes dated 8/07/2023 and 8/09/2023 because sometimes it could be charted in one of our systems and not another, and that was her guess. The FA indicated Venofer was given 8/11/2023, and it was due to be administered weekly, and the Charge Nurse indicated she didn't know why Venofer was administered on 8/21/2023. 3. Record review for Patient #7 (admit date 6/19/2023) evidenced an undated document titled "Lab Results", which evidenced the patient's Hgb level was tested weekly, and dropped from 11.2 on 6/19/2023, to 8.0 on 8/14/2023. The clinical record failed to evidence the IDT addressed the low hemoglobin status. During an interview on 8/25/2023 at 2:38 PM, the Regional Social Work Manager (corporate) indicated they were out of compliance with the plan of care (POC), they should have had IDT meetings, and created a POC.	V 547			
V 550	POC-VASCULAR ACCESS-MONITOR/REFERRALS CFR(s): 494.90(a)(5) The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access.	V 550			

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V 550	<p>Continued From page 79</p> <p>The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the facility failed to ensure the patient's access site was washed prior to treatment in 7 of 8 initiations of treatment through a fistula. (PCT 1, PCT 5, PCT 9)</p> <p>These findings include:</p> <ol style="list-style-type: none"> 1. An agency procedure titled "Access Assessment and Cannulation, published 5/2/2022, stated, "Prior to treatment ask your patient to watch accessorial liquid soap for one minute, rinsing well. Dry with a clean paper towel. Wash access (per above) if patient unable to clean their access" 2. During an observation on 8/22/2023 at 11:35 AM, PCT 3 was observed at station #21 initiating dialysis for patient #28. PCT 3 failed to ensure Patient #28 washed his access. 3. During an observation on 8/22/2023 at 11:55 AM, PCT 3 was observed at station #22 initiating dialysis for patient #29. PCT 3 failed to ensure Patient #29 washed his access. 4. During an interview on 8/23/2023 at 3:38 PM, the Facility Adminstrator indicated Patients should stop and wash at the sink, if they are not able the PCT should wash at the chairside. 5. Observation of the treatment area on 	V 550			

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V 550	<p>Continued From page 80</p> <p>8/22/2023 at 11:24 AM revealed a used glove sitting on the edge of a sink marked "clean", and was hanging down into a trash can, which was nearly full of garbage. At 11:37 AM, observed Patient Care Technician (PCT) 1 use the sink with the dirty glove on it to obtain soap and water cloths to cleanse Patient #22's (station 1) vascular access site prior to cannulation.</p> <p>6. During an observation on 8/23/2023 at 10:40 AM, Patient #17 (station 10) walked past the sink near the entry of the treatment area without washing her arm, and PCT 5 failed to wash the patient's arm with soap and water prior to accessing the vascular access site.</p> <p>7. During an observation on 8/24/2023 at 11:25 AM, Patient #18 (station 14) walked past the sink near the entry of the treatment area without washing his arm, and the PCT failed to wash the patient's arm prior to accessing the vascular access site.</p> <p>8. During an observation on 8/24/2023 at 11:35 AM, Patient #20 (station 18) walked past the sink near the entry of the treatment area without washing his arm, and PCT 9 failed to wash the patient's arm prior to accessing the vascular access site.</p> <p>8. During an observation on 8/24/2023 at 11:44 AM, Patient #21 (station 21) walked past the sink near the entry of the treatment area without washing his arm, and PCT 9 failed to wash the patient's arm prior to accessing the vascular access site.</p> <p>9. During an interview on 8/24/2023 at 11:55 AM, PCT 9 described the procedure for accessing the</p>	V 550			

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V 550	Continued From page 81 vascular site, but failed to include the site must be washed with soap and water prior to applying skin antiseptic. 10. During an interview on 8/23/2023 at 3:38 PM, the Facility Administrator (FA) indicated the patients should stop by the sink to wash their arms, and if not able, the PCT should. 11. During an interview on 8/24/2023 at 3:15 PM the FA indicated PCTs should ask the patients if they washed their arms if they didn't observe it being done.	V 550			
V 551	POC-VA MONITOR/PREVENT FAILURE/STENOSIS CFR(s): 494.90(a)(5) The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure the patient's access site was monitored for symptoms of stenosis in 1 of 2 observations of initiating dialysis with a fistula. (PCT 2, PCT 5) These findings include: 1. An agency policy titled "Access Assessment and Cannulation," published 8/22/2018, stated, " ... Check fistula for adequate bruit and thrill to confirm patency ... Listen: bruit high pitch whistle bruit not present throughout access ...	V 551			

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V 551	Continued From page 82 document..." 2. During an observation on 8/23/2023 at 11:45 AM, PCT 5 was observed at station #10 initiating dialysis for patient #17. PCT 5 failed to auscultate Patient #17's access. 3. During an observation on 8/23/2023 at 1:50 PM, PCT 2 was observed at station #7 initiating dialysis for patient #33. PCT 2 failed to auscultate and palpate Patient #17's access. 4. During an interview on 8/23/2022 at 3:38 PM, the Facility Administrator indicated staff should auscultate and palpate the access every treatment.	V 551			
V 552	POC-P/S COUNSELING/REFERRALS/HRQOL TOOL CFR(s): 494.90(a)(6) The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis. This STANDARD is not met as evidenced by: Based on record review and interview, the interdisciplinary team (IDT) failed to ensure the patient received the necessary services to meet psychosocial needs for 1 of 1 recently admitted patient (Patient #7).	V 552			

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

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V 552	Continued From page 83 The findings include: Record review for Patient #7 (admit date 6/19/2023) failed to evidence the patient's psychosocial needs were addressed, or a referral was made for hospice services. During an interview on 8/25/2023 at 2:38 PM, the Regional Social Work Manager (corporate) indicated they were out of compliance with the plan of care (POC), they should have had IDT meetings, completed comprehensive assessments, and created POC. The Dietician indicated the patient should have been listed as unstable, due to his condition. The Charge Nurse indicated the patient moved up here to be with family because he had declined so much, and he would have probably benefited from hospice services. During an interview on 8/25/2023 at 3:08 PM, Person 1 (staff at Entity 1) indicated last Friday (8/18/2023), Patient #7 said he was "giving up, and didn't know if he wanted to continue (dialysis treatments)". Person 1 also indicated the patient had since passed away.	V 552			
V 559	POC-OUTCOME NOT ACHIEVED-ADJUST POC CFR(s): 494.90(b)(3) If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must- (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and	V 559			

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V 559	<p>Continued From page 84</p> <p>(iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the dialysis center failed to adjust the patient's plan of care the achieve the expected goals in 4 of 7 records reviewed. (Patient #1, #2, #3, and #4)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. An agency policy titled Comprehensive Interdisciplinary Assessment and Plan of Care published 7/3/2023, stated, " ... If the patient-specific expected outcome as determined by the attending physician, IDT and patient for the plan of care is not achieved within the identified time frame the interdisciplinary team must adjust the patient 's plan of care and document changes made to the plan of care and implement the plan of care changes to address the identified issues" 2. Clinical record review for patient #1, admit date 8/19/2022, evidenced a Plans of Care dated 9/16/2022 and 11/22/2022. These documents indicated the Patient was not meeting goals for the following areas of focus implemented on 9/16/2022 and 11/16/2022: Blood Pressure (BP) and Fluid Management, Fall Risk, Modality Education, Anemia Management, Change in Mental Status. Hospitalization within the last 90 days. Documentation indicated these areas of focus are "ongoing." The Dialysis Center failed to adjust and implement changes to the plan of care. 	V 559			

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V 559	<p>Continued From page 85</p> <p>3. Clinical record review for patient #2, admit date 2/7/2023, evidenced a Plan of Care dated 4/13/2023. The document indicated Patient #2 was not meeting goals in the following areas of focus implemented on 4/12/2023: Blood Pressure (BP) and Fluid Management, Fall Risk, Modality Education, Diabetes Management, and Anemia Management. Documentation indicated the patient was progressing and staff would continue to monitor. The Dialysis Center failed to adjust and implement changes to the plan of care.</p> <p>4. Clinical record review for patient #3, admit date 5/16/2022, evidenced a Plans of Care dated 6/16/2022 and 6/28/2023. These documents indicated the Patient was not meeting goals for the following areas of focus implemented on 6/16/2022 and 11/16/2022: Anemia Management, Mineral Metabolism/Bone Disease, and Albumin. Documentation indicated these areas of focus are "in progress." The Dialysis Center failed to adjust and implement changes to the plan of care.</p> <p>5. Clinical record review for patient #4, admit date 2/1/2022, evidenced a Plan of Care dated 6/28/2022. The document indicated Patient #2 was not meeting goals in the following areas of focus implemented on 6/15/2022: Dialysis Access, Blood Pressure (BP) and Fluid Management, Fall Risk, Diabetes Management, Hospitalization within the last 90 days, and Anemia Management. Documentation indicated the patient was progressing and staff would continue to monitor. The Dialysis Center failed to adjust and implement changes to the plan of care.</p> <p>During an interview on 8/28/23 at 1:37 PM, the Dietician indicated they had an in-service on</p>	V 559			

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

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FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152520	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 08/29/2023
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NEPHROLOGY MISHAWAKA			STREET ADDRESS, CITY, STATE, ZIP CODE 710 PARK PL MISHAWAKA, IN 46545		
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V 559	Continued From page 86	V 559			
V 726	<p>pains of care in April (2023), which they clearly need to do again.</p> <p>MR-COMPLETE, ACCURATE, ACCESSIBLE CFR(s): 494.170</p> <p>The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.</p> <p>This STANDARD is not met as evidenced by: Based on observation record review and interview the agency failed to ensure records were accurate and complete in 4 of 7 records reviewed (Patient #1, #2, #3, #4)</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. An agency policy titled "Medical Record Documentation Standards." published 4/5/2021, stated, "The dialysis facility must monitor and maintain complete, accurate and accessible records on all patients" 2. Clinical record review on 8/24/2023 for Patient #1, start of care 8/19/2022, included a review of the dialysis treatment sheets from 7/26/2023 through 8/21/2023 and evidenced the following: The flowsheets dated 7/31/2023, 8/4/2023, 8/7/2023, 8/11/2023, and 8/21/2023 evidenced Patient #1 had no new complaints or observations during the PCT 4's pretreatment assessment. PCT 4 documented Patient #1's pretreatment complaints improved by the end of 	V 726			

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V 726	<p>Continued From page 87</p> <p>dialysis. The agency failed to ensure Patient #1's treatment record contained accurate information.</p> <p>The flowsheet dated 8/18/2023 evidenced Patient #1 had no new complaints or observations during the PCT 8's pretreatment assessment. PCT 8 documented Patient #1's pretreatment complaints improved by the end of dialysis. The agency failed to ensure Patient #1's treatment record contained accurate information.</p> <p>The flowsheet dated 8/4/2023, 8/7/2023, and 8/21/2023 Registered Nurse (RN) 2 documented Patient #1 had no edema, but also documented he had edema in his bilateral lower legs and ankles. The agency failed to ensure Patient #1's treatment record contained accurate information.</p> <p>The flowsheet dated 7/28/2023, 7/31/2023, 8/4/2023, 8/7/2023, and 8/11/2023 RN RN 3 documented Patient #1 had no edema, but also documented he had edema in his bilateral lower legs and ankles. The agency failed to ensure Patient #1's treatment record contained accurate information.</p> <p>3. Clinical record review on 8/24/2023 for Patient #2, start of care 2/7/2023, included a review of the dialysis treatment sheets from 7/25/2023 through 8/19/2023 and evidenced the following:</p> <p>The flowsheet dated 7/27/2023,8/1/2023, 8/3/2023, 8/5/2023, 8/8/2023, 8/10/2023, 8/15/2023, 8/17/2023, and 8/19/2023 evidenced Patient #2 had no new complaints or observations during the PCT's pretreatment assessment. The PCT documented Patient #2's pretreatment complaints improved by the end of dialysis. The agency failed to ensure Patient #2's</p>	V 726			

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V 726	<p>Continued From page 88</p> <p>treatment record contained accurate information.</p> <p>The flowsheet dated 7/27/2023 evidenced Patient #2 had complaints of nausea at 3:31 PM, PCT 2 documented there were no new findings or complaints during dialysis. The agency failed to ensure accurate documentation in the treatment record.</p> <p>The flowsheet dated 8/3/2023 evidenced Patient #2 had received Tylenol (for pain) at 3:10 PM, at 4:10 PM, the nurse documented the symptoms were "relieved." The record failed to indicate why the Tylenol was given, at 4:21 PM Patient #2 had complaints of pain in the neck and shoulder and wanted to discontinue treatment. Treatment was discontinued at 4:22 PM, the nurse documentation at 4:53 indicated the Patient left in a wheelchair and had no complaints of changes in condition. PCT 5 documented there were no new findings or complaints during dialysis. The agency failed to ensure accurate documentation in the treatment record.</p> <p>The flowsheet dated 8/8/2023 evidenced Patient #2 had complaints of not being able to breathe and her BP dropped. Her prescribed BFR was 500 and her prescribed DFR was 800. The document evidenced a note written by RN #2 which indicated her prescribed DFR was 500 and the patient had no complaints or change of condition during treatment. The agency failed to ensure accurate documentation in the treatment record.</p> <p>The flowsheet dated 7/27/2023 8/10/2023 RN 2 documented Patient #2 had no edema, but also documented he had edema in his bilateral lower legs and ankles. The agency failed to ensure</p>	V 726			

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V 726	<p>Continued From page 89</p> <p>Patient #2's treatment record contained accurate information.</p> <p>The flowsheet dated 8/15/2023 evidenced Patient #2 received Tylenol at 2:18 PM. The document failed to evidence why the patient was given Tylenol.</p> <p>The flowsheet dated 8/19/2023 evidenced Patient #2 received Tylenol at 2:01 PM. The document failed to evidence why the patient was given Tylenol.</p> <p>4. Clinical record review on 8/24/2023 for Patient #3, start of care 5/16/2019, included a review of the dialysis treatment sheets from 7/28/2023 through 8/21/2023 and evidenced the following:</p> <p>The flowsheets dated 7/31/2023, 8/4/2023, 8/9/2023, 8/11/2023, 8/14/2023, and 8/18/2023, RN 3 documented Patient #3 had no edema, but also documented she had edema in her bilateral lower legs and ankles. The agency failed to ensure Patient #3's treatment record contained accurate information.</p> <p>The flowsheets dated 8/4/2023, and 8/11/2023, evidenced Patient #3 had no new complaints or observations during the PCT's pretreatment assessment. The PCT documented Patient #3's pretreatment complaints improved by the end of dialysis. The agency failed to ensure Patient #3's treatment record contained accurate information.</p> <p>The flowsheet dated 8/21/2023, RN 2 documented Patient #3 had no edema, but also documented she had edema in her bilateral lower legs and ankles. The agency failed to ensure Patient #3's treatment record contained accurate</p>	V 726			

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V 726	<p>Continued From page 90 information.</p> <p>5. Clinical record review on 8/24/2023 for Patient #4, start of care 2/1/2022, included a review of the dialysis treatment sheets from 5/4/2023 through 5/30/2023 and evidenced the following:</p> <p>The flowsheet dated 5/13/2023, evidenced Patient #4 had no new complaints or observations during the PCT's pretreatment assessment. The PCT documented Patient #4's pretreatment complaints improved by the end of dialysis. The agency failed to ensure Patient #4's treatment record contained accurate information.</p> <p>The flowsheet dated 5/16/2023, 5/23/2023, and 5/25/2023 RN 2 documented Patient #4 had no edema, but also documented she had edema in her bilateral lower legs and ankles. The patient experienced cramping during treatment, the RN failed to document the cramping and if the cramping resolved. The agency failed to ensure Patient #3's treatment record contained complete and accurate information.</p> <p>The flowsheet dated 5/16/2023 and 5/30/2023 documented Patient #4 experienced cramping during treatment, the RN failed to document the cramping and if the cramping resolved. The agency failed to ensure Patient #3's treatment record contained complete information.</p> <p>During an interview on 8/29/2023 at 1:13 PM, the Facility Administrator indicated all patient records should be complete and accurate. She did not know why the system was showing no edema and then documentation of edema. She indicated it should not be documented like that.</p>	V 726			