

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

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FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152501	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 02/22/2024
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE GARY	STREET ADDRESS, CITY, STATE, ZIP COD 3290 GRANT ST GARY, IN 46408
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E 0000 Bldg. 00	An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62. Survey Dates: February 14, 15, 16, 19, 20, 21, and 22, 2024 Active Census: 102 At this Emergency Preparedness survey, Fresenius Medical Care Gary was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.	E 0000		
V 0000 Bldg. 00	This visit was for a Federal complaint survey of an ESRD provider. Survey dates: February 14, 15, 16, 19, 20, 21, and 22, 2024 Complaint IN00428274 was investigated with related and unrelated deficiencies cited. A full Federal CORE survey was announced to the Administrator on 02/16/24 at 10:05 AM. Census by Service Type: In-Center Hemodialysis: 89 Home Hemodialysis: 0 Home Peritoneal dialysis: 13	V 0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Geralyn Vogel	Sr. Regulatory Manager	03/29/2024

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

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V 0110 Bldg. 00	<p>Total Active Census: 102</p> <p>Isolation Room/Waiver: 1</p> <p>The Administrator and Clinic Manager were notified on 02/19/24 at 3:22 PM of an Immediate Jeopardy at 42 CFR 494.70 Patients' Rights. The Immediate Jeopardy was identified as beginning on 2/09/2024. The immediacy was not abated prior to survey exit on 2/22/24.</p> <p>During this Federal complaint survey, Fresenius Medical Care Gary was found out of compliance with Conditions for Coverage at 42 CFR 494.30 Infection control, 494.70 Patients' Rights, and 494.90 Patient plan of care.</p> <p>QR: 03/01/2024 A 1</p> <p>494.30 CFC-INFECTION CONTROL</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure they maintained a sanitary environment specific to the mixing and storage of bleach solutions (See V111), failed to ensure staff completed hand hygiene according to hand hygiene policies and procedures (See V113), failed to ensure staff completed disinfection of dialysis stations according to facility policies and procedures (See V122), failed to ensure staff followed best practice and disinfected the connection hub of the central venous catheter prior to administering intravenous medication (See V143), and failed to ensure staff performed central venous catheter (CVC) site care according to facility policies and procedures (See V147).</p>	V 0110	The Governing Body of this facility acknowledges its responsibility to ensure the facility maintains a sanitary environment, inclusive of, but not limited to, the mixing and storage of bleach solutions, to ensure staff complete hand hygiene, the disinfection of the dialysis station, the disinfection of the central venous catheter (CVC) connection hub prior to administering intravenous medications, as well as, the disinfection and care of the CVC exit site per policy and procedure, as required.	03/22/2024

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	<p>The cumulative effect of these systemic issues resulted in the facility being unable to provide adequate infection control measures. Therefore, Fresenius Medical Care Gary was found out of compliance with Conditions of Coverage 494.30 Infection control.</p>		<p>As such, the Governing Body held a conference call on 2/26/24 to review the information provided by the surveyors during this survey and actively participate in the development of the Plan of Correction. The Governing Body has committed to meet weekly to review the status of the Plan of Correction until all issues are resolved and the facility is back in compliance.</p> <p>The Governing Body met again on 3/18/24, to review the Statement of Deficiencies and develop the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution.</p> <p>The Governing Body began meeting weekly beginning 2/26/24 to review the results of the progress on the Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The Governing Body will determine when the frequency of these meetings may be reduced to the regular quarterly schedule. Effective immediately:</p> <p>-The Clinical Manager will analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee.</p>	

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			<p>-A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda.</p> <p>-The QAI Committee is responsible for reviewing and evaluating the Plan of Correction to ensure it is effective and providing resolution of the issues.</p> <p>-The Facility Administrator will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>-The Governing Body, at its meeting of 2/26/24, designated the Facility Administrator to serve as Plan of Correction Monitor and provide additional oversight. They will participate in QAPI and Governing Body meetings. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement of Deficiency through to resolution as well as ensure the Governance of the Facility is presented current and complete data to enhance their governance oversight role.</p> <p>Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide</p>	

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V 0111 Bldg. 00	<p>494.30 IC-SANITARY ENVIRONMENT 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>Based on observation, policy review, and interview, the dialysis clinic failed to maintain a sanitary environment specific to the mixing and storage of bleach solutions used for disinfection of the dialysis stations and clamps, which had the potential to affect all in-center hemodialysis (ICHD) patients in 4 of 5 observations of the incenter dialysis treatment floor.</p> <p>Findings include:</p> <p>1. The review of facility policy #47806 titled "Cleaning and Disinfecting the Dialysis Station," dated 09/05/23, indicated bleach solution should be stored in a covered container "to prevent disintegration of the chemical (sodium hypochlorite) when exposed to sunlight and air."</p>	V 0111	<p>evidence of these actions, the Governing Body's direction, and oversight and the QAI Committees ongoing monitoring of facility activities. These are available for review at the facility.</p> <p>The responses provided for V 111, V 113, V 122, V 143, and V 147 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies cited within this Condition are corrected to ensure ongoing compliance.</p> <p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on the policy listed below. On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> ·Mixing Bleach version 4 <p>Emphasis was placed on:</p>	03/22/2024

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	<p>2. The review of facility policy titled "Mixing Bleach," dated 8/25/20, indicated when preparing the 1:10 concentration bleach solution, staff should mix 1 milliliter (mL) bleach for every 9 mL of water. When preparing the 1:100 concentration bleach solution, staff should mix 1 mL bleach for every 99 mL of water. The policy indicated the container with the bleach solution should be labeled with the solution's concentration and covered with a lid.</p> <p>3. During an observation on the in-center hemodialysis treatment floor on 2/14/24 beginning at 8:20 AM, one container of bleach solution was observed open.</p> <p>4. During an observation on the ICHD treatment floor on 2/19/24, the following was observed:</p> <p>a. At 8:32 AM, one container of bleach solution with clamps sitting in the solution was observed open.</p> <p>b. At 8:45 AM, one container of bleach solution was observed open and sitting at a clean handwashing sink.</p> <p>c. At 8:57 AM, one container of bleach solution was observed open.</p> <p>d. At 10:55 AM, one container of bleach solution was observed open and sitting at a clean handwashing sink. Patient Care Technician (PCT) 3 was observed washing his/her hands at the sink. At 10:57 AM, PCT 1 was observed dipping a clean gauze pad into the bleach solution and left the container open as he/she left the handwashing station. The technician used the bleach-soaked gauze pad to clean an ICHD</p>		<p>·Pour measure amount of water needed into a labeled opaque container.</p> <p><u>·Measuring ensures proper concentration:</u></p> <p><u>·1:100 = 1-part bleach + 99 parts water</u></p> <p><u>·1:10 = 1-part bleach + 9 parts water</u></p> <p><u>1:10 dilution- 1ml bleach: 9ml of water</u></p> <p><u>1:100 dilution- 1ml bleach: 99ml of water</u></p> <p>·Slowly pour measured amount of bleach into measured water in opaque container. Mix solution.</p> <p><u>·Label opaque container with "Bleach Solution", strength of solution, date, and time prepared and your initials.</u></p> <p><u>·Cover opaque container with lid.</u></p> <p>On 3/7/24, the Clinical Manager implemented daily audits with focus on ensuring bleach solution is mixed and stored per policy utilizing the Clinic Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Audits will continue daily until receipt of the Statement of Deficiencies and then will be re-evaluated at that time.</p> <p>Effective 3/21/24, Clinical Manager will conduct daily audits with focus on ensuring bleach solution is mixed and stored per policy</p>	

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	<p>dialysis station.</p> <p>e. At 11:16 AM, one container of bleach solution was observed open and sitting at a clean handwashing sink. PCT 7 was observed washing his/her hands at the sink.</p> <p>5. During an observation on the ICHD treatment floor on 2/20/24 at 9:02 AM, one container of bleach solution was observed open and sitting at a clean handwashing sink. PCT 5 was observed washing his/her hands at the sink with the open beach container.</p> <p>6. During an interview with PCT 1 on 2/21/24 beginning at 8:14 AM, the technician reported he/she made 2 of the 4 bleach solutions being used on the ICHD treatment floor. PCT 1 reported one container was 1 part bleach to 10 parts water (1:10 concentration) and the other was 1:100 concentration. The technician stated when preparing the 1:10 bleach solution, he/she would measure out 50 milliliters (mL) bleach, and when preparing the 1:100 bleach solution, he/she would measure out 10 milliliters (mL) bleach.</p> <p>During an observation on the ICHD treatment floor on 2/21/24 at 8:21 AM, a sign on the treatment floor was observed with instructions on how to prepare bleach solutions. For 1:10 bleach solution, staff were to mix 10 mL bleach to 990 mL water. For 1:100 bleach solution, staff were to mix 10 mL bleach and 900 mL water.</p> <p>During a follow-up interview with PCT 1 on 2/21/24 beginning at 8:22 AM, the technician reported when preparing the 1:10 concentration bleach solution, he/she would mix 50 mLs bleach with 1000 mLs water. For the 1:100 concentration bleach solution, PCT 1 would mix 10 mLs bleach</p>		<p>requirements utilizing Clinic Audit Tool for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p>	

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	<p>with 1000 mLs water. The technician showed the surveyor the male urinal container staff used to measure out water and pointed to the 1000 mL marker, indicating this was the line PCT 1 filled the water to when mixing both 1:10 and 1:00 bleach solutions.</p> <p>During an observation on the ICHD treatment floor on 2/21/24 beginning at 10:21 AM, PCT 1 soaked 4x4 cloth pads in the container which the PCT had previously indicated was 1:100 concentration bleach solution made with 10 mLs bleach and 1000 mLs water. The technician used the soaked gauze pads to clean Station #19.</p> <p>During an observation on the ICHD treatment floor on 2/21/24 beginning at 10:37 AM, PCT 4 soaked 4x4 gauze pads in the container which PCT 1 had previously indicated was 1:100 concentration bleach solution made with 10 mLs bleach and 1000 mLs water. The technician used the soaked cloth pads to clean Station #2.</p> <p>7. During an interview with PCT 5 on 2/21/24 beginning at 10:48 AM, the technician reported he/she made 2 of the 4 bleach solutions being used on the ICHD treatment floor. PCT 5 stated the container sitting at a clean handwashing sink was 1:10 concentration and the container at a dirty sink was 1:100 concentration. The container indicated as 1:100 concentration was observed to be labeled "1:100 concentration" and had clamps soaking in it. PCT 5 reported he/she prepared the 1:100 concentration bleach solution using 10 mLs bleach and 1000 mLs water. The technician stated the container he/she used to measure the water was not on the treatment floor at that time. PCT 5 and surveyor observed the container sitting at the clean handwashing sink failed to evidence a label with the concentration of the solution. PCT 5</p>		<p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p>	

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	<p>stated this solution would need to be remade as the container failed to evidence a label.</p> <p>During a follow-up interview with PCT 5 on 2/21/24 beginning at 12:50 PM, the technician reported the container sitting at the clean handwashing sink was 1:100 concentration bleach solution and the container at the dirty sink with clamps soaking in it was 1:10 concentration. PCT 5 stated both bleach solutions would need to be remade as the containers failed to evidence they were clearly marked with the solution's concentration. The technician showed the surveyor the male urinal container used to measure out water when preparing the bleach solution. PCT 5 reported when making 1:100 concentration bleach solution, he/she mixed 10 mL bleach with 990 mLs water. When asked to point to the marking on the male urinal container that was 990 mLs water, PCT 5 pointed to the marking for 975 mLs. The male urinal container used to measure water failed to evidence a marking for 990 mLs.</p> <p>8. During an interview with Clinic Manager 2 on 2/21/24 beginning at 1:20 PM, the clinic manager reported when staff were preparing 1:10 concentration bleach solution, they should mix 10 mLs bleach with 900 mLs water. When preparing 1:100 concentration bleach solution, staff should mix 10 mLs bleach with 990 mL water. Clinic Manager 2 reported staff used a male urinal container to measure water for the bleach solution. When asked to point to the marking on the male urinal container that was 990 mL, the clinic manager pointed to the marking for 975 mLs.</p> <p>9. During an interview with Administrator and Clinic Manager 2 on 2/20/24 beginning at 4:20 PM, Clinic Manager 2 reported the bleach containers</p>			

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V 0113 Bldg. 00	<p>should be stored with the lid on.</p> <p>10. During an interview on 2/20/24 at 10:00 AM, Registered Nurse (RN) 4 indicated the bleach containers should remain closed.</p> <p>11. During an observation of the ICHD treatment area on 2/22/2023 at 9:57 AM, one container of bleach solution was observed sitting open on the counter across from the nurse's station.</p> <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE 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>Based on observation, policy review, and interview, the dialysis facility failed to ensure staff completed hand hygiene according to hand hygiene policies and procedures during 3 of 4 days of in-center hemodialysis (ICHD) treatment floor observations (Patient Care Technicians (PCT) 2, 5, 7, 8, 9).</p> <p>Findings include:</p> <p>1. The review of facility policy #47664 titled "Hand Hygiene," dated 11/06/23, indicated hand hygiene should be performed before and after direct contact with patients, when entering and leaving the treatment area, and immediately after removing gloves. The policy also indicated when performing hand hygiene by washing hands with soap and water, the procedure should last "40 - 60 seconds."</p> <p>2. During an observation on the ICHD treatment floor on 2/19/24, the following was observed:</p>	V 0113	<p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on policies listed below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> ·Hand Hygiene version 8 ·Personal Protective Equipment version 6 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> ·Hands will be washed with antimicrobial soap and water: 	03/22/2024

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	<p>a. At 9:17 AM, Patient Care Technician (PCT) 7 was observed leaving Station #7. The technician removed his/her gloves, walked to a supply station, donned new gloves, and re-entered Station #7. PCT 7 failed to perform hand hygiene in between glove change.</p> <p>b. At 9:42 AM, PCT 2 was observed removing his/her gloves, adjusting his/her mask, donning new gloves, and entering Station #7. PCT 2 failed to perform hand hygiene in between glove change.</p> <p>c. At 9:43 AM, PCT 7 was observed assisting Patient #9 holding pressure to his/her arteriovenous (AV) fistula site, which had bled through the gauze. PCT 7 cleaned the excess blood from the patient's skin, discarded the bloodied gauze and barrier, removed his/her gloves, and washed his/her hands for less than 5 seconds. PCT 7 then entered Station #20 and donned gloves.</p> <p>During an interview with PCT 7 on 2/20/24 beginning at 9:59 AM, the technician reported hand hygiene should be performed prior to donning new gloves.</p> <p>d. At 10:34 AM, PCT 2 was observed drawing up Heparin (a blood thinner medication) from a multi-dose vial at the medication preparation area. The technician took the medication vial to Station #8, changed his/her gloves, and injected the medication into Patient #10's Central Venous Catheter (CVC). The technician failed to perform hand hygiene in between glove changes.</p> <p>During an interview with PCT 2 on 2/20/24 beginning at 9:40 AM, the technician reported</p>		<ul style="list-style-type: none"> ·Hands are visibly dirty or contaminated with proteinaceous material, blood, or other body fluids ·Before eating ·After using a restroom ·Anthrax or C-difficile exposure ·Hands will be decontaminated using alcohol-based hand dry or by washing hands with antimicrobial soap and water: <u>·Before and after direct contact with patients</u> ·Entering and leaving the treatment area ·Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications ·<u>Immediately after removing gloves</u> ·After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled ·<u>After contact with inanimate objects near the patient</u> ·When moving from a contaminated body site to a clean body site of the same patient After contact with the dialysis wall box, concentrate, drain, or water lines, ·<u>After contact with other objects within the patient station or treatment space</u> ·<u>When washing hands with soap and water, duration of the entire</u> 	

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	<p>hand hygiene should be performed "every time" he/she takes off gloves.</p> <p>e. At 10:36 AM, PCT 7 was observed washing his/her hands for less than 5 seconds.</p> <p>f. At 11:16 AM, PCT 7 was observed washing his/her hands for 12 seconds.</p> <p>g. At 11:31 AM, PCT 9 entered Station #3 with ungloved hands. The technician placed tape on the patient's drape, donned 1 glove, obtained additional supplies from the supply station in the middle of the treatment floor, and donned a second glove. PCT 9 opened supply packaging, left the station to throw away trash, and adjusted his/her face shield as re-entering Station #3. PCT 9 then began initiating Patient #30's dialysis using an AV fistula.</p> <p>3. During an observation on the ICHD treatment floor on 2/20/24, the following was observed:</p> <p>a. At 8:50 AM, PCT 7 was observed to wash his/her hands for 5 seconds.</p> <p>b. At 9:03 AM, PCT 5 was observed to wash his/her hands for 20 seconds.</p> <p>5. During an observation on the ICHD treatment floor on 2/21/24 at 9:49 AM, PCT 8 was observed in Station #16 with Patient #32. The technician was observed and changed his/her gloves, though failed to perform hand hygiene in between glove changes.</p> <p>6. During an interview with Administrator and Clinic Manager 2 on 2/20/24 beginning at 4:20 PM, the administrative staff reported staff should perform hand hygiene in-between glove changes,</p>		<p><u>procedure: 40-60 seconds</u></p> <p><u>·When decontaminating hands with alcohol-based hand rubs.</u></p> <p><u>duration of the entire procedure: 20-30 seconds</u></p> <ul style="list-style-type: none"> ·Staff must remove gloves and wash hands after: ·Patient care ·Exposure to blood and body fluids ·Touching any surfaces within the patient station <p><u>·Always perform hand hygiene after glove removal.</u></p> <p>On 3/7/24, the Clinical Manager implemented daily audits with focus on ensuring staff complete hand hygiene according to hand hygiene policy and procedure as required utilizing the Clinic Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Audits will continue daily until receipt of the Statement of Deficiencies and then will be re-evaluated at that time.</p> <p>Effective 3/21/24, Clinical Manager will conduct daily audits with focus on ensuring staff complete hand hygiene according to hand hygiene policy and procedure as required utilizing Clinic Audit Tool for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine</p>	

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	<p>after removing gloves, and after handing items that soiled or have visible blood.</p> <p>7. During an observation of the ICHD treatment floor on 2/20/24, the following was observed:</p> <p>a. At 9:20 AM, PCT 2 was observed writing on the daily schedule. PCT 2 then donned gloves and began to set up the dialysis machine at Station #2; PCT 2 failed to perform hand hygiene prior to donning gloves.</p> <p>b. At 9:25 AM, PCT 5 was observed he/she washed their hands with soap and water, they completed the entire hand-washing procedure, including drying their hands, in 8 seconds.</p> <p>c. At 9:33 AM, PCT 5 was observed washing his/her hands with soap and water after removing needles for the Patient at Station #18. PCT 3 completed the entire hand-washing procedure, including drying his/her hands, in 7 seconds.</p> <p>d. At 9:50 AM, PCT 5 was observed washing his/her hands with soap and water. PCT 3 completed the entire hand-washing procedure, including drying his/her hands, in 6 seconds.</p> <p>8. During an interview on 2/20/24 at 9:53 AM, PCT 5 indicated handwashing was to be done in between patients and when hands are soiled. The technician indicated hands should be scrubbed for a minimum of 20 seconds with soap and water.</p>		<p>on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by</p>	

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V 0122 Bldg. 00	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [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>Based on observation, policy review, and interview, the dialysis facility failed to ensure staff completed disinfection of dialysis stations according to facility policies and procedures and best practice in 5 of 6 observation of staff disinfecting a dialysis station (Patient Care Technicians (PCT) 1, 2, 9).</p> <p>Findings include:</p> <p>1. The review of the facility policy #47806 titled "Cleaning and Disinfecting the Dialysis Station," dated 09/05/23, indicated when disinfecting a dialysis station, staff should open the side panels of a treatment chair to disinfect all chair surfaces. "Special attention" should be paid to cleaning the</p>	V 0122	<p>the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p> <p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on the policy listed below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <p>·Cleaning and Disinfection of the</p>	03/22/2024

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	<p>control panel on the dialysis machine "and other surfaces that are frequently touched and potentially contaminated with patients' blood / bodily fluids." The policy indicated 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" should be disinfected. The policy also indicated staff should allow all surfaces to air dry.</p> <p>2. During an observation on 2/19/24 beginning at 8:52 AM, PCT 9 was observed cleaning Station #4 after the patient left the treatment floor. PCT 9 failed to open and clean the chair's side panels. While the station was visibly wet with bleach, PCT 9 placed new supplies on the chair's side table.</p> <p>3. During an observation on the ICHD treatment floor, PCT 9 was observed cleaning Station #3 after the patient left the treatment floor. PCT 9 failed to open and clean the chair's side panels.</p> <p>During an interview with PCT 9 on 2/19/24 beginning at 3:59 PM, the technician reported when cleaning a dialysis station after use, the treatment chair's side panels should be opened and wiped down with a bleach pad. PCT 9 reported the station should be allowed to dry for 30 - 60 seconds prior to placing new equipment in the station.</p> <p>5. During an observation on the ICHD treatment floor on 2/21/24 beginning at 10:21 AM, PCT 1 was observed cleaning Station #19 after the patient left the treatment floor. While wiping down the dialysis machine, the technician failed to clean the top of the IV pole where the saline bag had hung. After wiping down the machine and prior to</p>		<p>Dialysis Station version 14</p> <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -The dialysis station could become contaminated with blood and other body fluids during treatment. After use, any non-disposable equipment and supplies brought into the dialysis station must be disinfected with 1:100 bleach or EPA registered disinfectant before being removed from the dialysis station. -Use a cloth wetted with 1:100 bleach solution or EPA-approved disinfectant to clean and disinfect the dialysis station (<u>chair/bed, tables, machine, television, IV pole, B/P cuff, hand sanitizer dispenser and holder, prime waste bucket, chaise wall behind chair</u>). <u>Place the chair in Trendelenburg position and open side panels if chair has swing open sides so all surfaces of the chair are accessible.</u> Give special attention to the cleaning control panel on the dialysis machine and other surfaces that are frequently touched and potentially contaminated with patient's blood and/or body fluids. <u>While wiping, remember to wipe all 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.</u> -All work surfaces shall be cleaned and disinfected with 1:100 	

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	<p>cleaning the treatment chair, PCT 1 took a new saline bag to the station, hung it on the IV pole, and connected blood line tubing. PCT 1 then began cleaning the station's chair. The technician wiped the chair's side panels then immediately closed them, failing to allow the side panels to dry.</p> <p>6. During an interview with Administrator and Clinic Manager 2 on 2/20/24 beginning at 4:20 PM, the administrative staff indicated when disinfecting a dialysis station, staff should wipe down the entire station, including opening the chair and wiping down all sides. The administrative staff indicated the dialysis machine should be wiped down from top to bottom, including the IV pole, BP cuff and tubing, and back of the machine. Clinic Manager 2 stated staff should leave the chair side panels open to allow the bleach solution to dry.</p> <p>7. During an observation on 2/20/24 at 9:15 PM, PCT 2 was observed cleaning Station #2. PCT 2 failed to clean the IV pole, failed to clean inside the blood pump door, and failed to clean the shelf behind the station. PCT 2 failed to remove the standard blood pressure cuff that remained in the basket and failed to clean the side of the dialysis machine. PCT 2 cleaned a large blood pressure cuff and then placed it on the dirty shelf.</p> <p>8. During an interview on 2/20/24 at 9:20 AM, PCT 2 indicated when cleaning the station, the entire machine needs to be wiped down, including opening all doors, wiping the sides and back of the machine, the dialysate lines, and machine shelf. The technician indicated the blood pressure cuff should be cleaned and the chair should have the sides opened and be fully reclined.</p>		<p>bleach solution after completion of procedures. <u>Make the surface glisteningly wet and allow to air dry</u> unless otherwise specified by the manufacturer.</p> <p>-To prevent cross-contamination between patients, it is important that the previous patient completely vacates the station before staff begin cleaning and disinfection of the station and set up for the next patient.</p> <p><u>-For patients dialyzing in a treatment area where multiple patients dialyze, the patient must completely vacate the dialysis station before the dialysis machine can be externally disinfected, allowed to dry and set up for the next treatment.</u></p> <p>On 3/7/24, the Clinical Manager implemented daily audits with focus on ensuring staff thoroughly and completely disinfect the dialysis station, as well as, allowing it to dry completely prior to bringing clean supplies into the station for set-up utilizing the Clinic Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Audits will continue daily until receipt of the Statement of Deficiencies and then will be re-evaluated at that time.</p> <p>Effective 3/21/24, Clinical Manager will conduct daily audits with focus</p>	

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			<p>on ensuring staff thoroughly and completely disinfect the dialysis station, as well as, allowing it to dry completely prior to bringing clean supplies into the station for set-up utilizing Clinic Audit Tool for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as</p>	

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V 0143 Bldg. 00	<p>494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [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</p> <p>Based on observation and interview, the dialysis facility failed to ensure staff followed best practice when disinfecting the connection hub a central venous catheter (CVC) prior to administering intravenous medication for 1 of 1 observations of staff discontinuing in-center hemodialysis (ICHD) using a CVC (Patient Care Technician (PCT) 9) and 1 of 4 observations of staff initiating ICHD using a CVC (PCT 3).</p>	V 0143	<p>appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p> <p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on the policy listed below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the</p>	03/22/2024

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	<p>Findings include:</p> <p>1. During an observation at Station #4 on 2/19/24 beginning at 8:37 AM, Patient Care Technician (PCT) 9 was observed disconnecting Patient #12 from his/her dialysis using a Central Venous Catheter (CVC, a long catheter placed into a large vein). After disconnecting the dialysis blood line from the first CVC hub, PCT 9 scrubbed the hub for 5 seconds with a 70% alcohol pad then connected a saline syringe. PCT 9 repeated the procedure with the second CVC hub, scrubbing the hub for 3 seconds with a 70% alcohol pad.</p> <p>During an interview with PCT 9 on 2/19/24 beginning at 3:59 PM, the technician reported the CVC hub should be scrubbed for 30-60 seconds prior to connecting any syringes or dialysis tubing.</p> <p>2. During an observation at Station #9 on 2/19/24 beginning at 10:18 AM, PCT 3 was observed initiating Patient #6's dialysis using a CVC. After connecting a saline syringe to the first CVC hub, the technician scrubbed the second hub with a 70% alcohol pad for 4 seconds then connected a saline syringe.</p> <p>During an interview with PCT 3 on 2/19/24 beginning at 4:04 PM, the technician reported the CVC hub should be scrubbed for 15 seconds prior to connecting any syringes or dialysis tubing.</p> <p>3. During an interview with Administrator and Clinic Manager 2 on 2/20/24 beginning at 4:20 PM, Clinic Manager 2 reported staff should scrub the hub of a CVC with an alcohol pad for 10-15 seconds prior to connecting a syringe or dialysis tubing.</p>		<p>Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> -Initiation of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer version 7 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -Threads and end of the luer lock (hub) must be scrubbed with 70% sterile alcohol pad <u>for 10-15 seconds</u> any time caps are removed, or bloodlines are disconnected (i.e. end of treatment or treatment interruption) to reduce risk of contamination. <p>On 3/7/24, the Clinical Manager implemented daily audits with focus on ensuring staff disinfect the hub for 10-15 seconds any time the caps are removed, or bloodlines are disconnected utilizing the Clinic Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Audits will continue daily until receipt of the Statement of Deficiencies and then will be re-evaluated at that time.</p> <p>Effective 3/21/24, Clinical Manager will conduct daily audits with focus on ensuring staff disinfect the hub</p>	

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			<p>for 10-15 seconds any time the caps are removed, or bloodlines are disconnected utilizing Clinic Audit Tool for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to</p>	

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V 0147 Bldg. 00	<p>494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>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.</p> <p>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</p>		<p>develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p>	

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	<p>suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>Based on observation, policy review, and interview, the dialysis facility failed to ensure all staff followed central venous catheter (CVC) site care according to facility policies and procedures for 3 of 3 observations of staff performing CVC exit site care (Patient Care Technician (PCT) 1, 2, and 3).</p> <p>Findings include:</p> <p>1. The facility procedure #45664 titled "Changing the Catheter Dressing Procedure," dated 2/05/24, indicated when changing the dressing on a central venous catheter (a long catheter placed in a large vein for dialysis), staff should disinfect the area around the catheter's insertion site, allow the disinfect to dry, and then place a new sterile dressing to the site.</p> <p>2. During an observation at Station #9 on 2/19/24 beginning at 10:18 AM, PCT 3 was observed performing site care to Patient #6's CVC. PCT 3 cleaned the site with a disinfectant swab beginning at the base of the catheter and going towards the insertion point. After cleaning the catheter site, Patient #6's shirt touched the</p>	V 0147	<p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on the policy listed below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> -Changing the Catheter Procedure version 8 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -Remove swabstick from package by stick end without touching foam applicator. Handle only the stick portion. 2% Chlorhexidine and 70% alcohol: <u>Using gentle back and forth friction. clean the exit site.</u> 	03/22/2024

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	<p>cleaned area prior to PCT 3 applying a new dressing.</p> <p>During an interview with PCT 3 on 2/19/24 beginning at 4:04 PM, the technician reported when performing site care to a CVC, the technician would begin cleaning at the base of the catheter, move the swab up towards insertion point, and take it down the other side of the catheter. PCT 3 reported the patient's clothing should be clamped or taped so it does not touch the cleaned site prior to applying a new dressing.</p> <p>3. During an observation at Station #8 on 2/19/24 beginning at 10:27 AM, PCT 2 was observed performing site care to Patient #10's CVC. PCT 2 cleaned the site with a disinfectant swab beginning at the base of the catheter and going towards the insertion point.</p> <p>4. During an observation at Station #16 on 2/19/24 beginning at 10:39 AM, PCT 1 was observed performing site care to Patient #28's CVC. PCT 1 cleaned the site with a disinfectant swab moving from the outer edges of the catheter to the insertion point. The technician failed to clean the site for 30 seconds.</p> <p>5. During an interview with Administrator and Clinic Manager 2 on 2/20/24 beginning at 4:20 PM, the administrative staff indicated the CVC site should be cleaned beginning at the insertion point and going outward.</p>		<p><u>beginning in the center and continuing outward the area of the size of the dressing to be applied (2 inches) in a concentric circle for 30 seconds and allow to dry a minimum of 30 seconds.</u> If exudate or crusting is noted, an additional swabstick may be necessary to clean the exit site.</p> <p>·Using aseptic technique, apply the catheter dressing over dry exit site, being careful not to touch the patient side of the dressing with gloved hands or to any surface.</p> <p>On 3/7/24, the Clinical Manager implemented daily audits with focus on ensuring the CVC exit site disinfection and care is performed per procedure as required utilizing the Clinic Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Audits will continue daily until receipt of the Statement of Deficiencies and then will be re-evaluated at that time.</p> <p>Effective 3/21/24, Clinical Manager will conduct daily audits with focus on ensuring the CVC exit site disinfection and care is performed per procedure as required utilizing Clinic Audit Tool for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency</p>	

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			<p>of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by</p>	

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V 0401 Bldg. 00	<p>494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT</p> <p>The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.</p> <p>Based on observation and interview, the dialysis facility failed to ensure all medication not immediately given was labeled with the intended patient's name for 2 of 2 medication syringes observed being stored for later use and failed to ensure the in-center hemodialysis (ICHD) treatment floor remained free of potential trip hazards for 1 of 4 days of ICHD treatment floor observations, which had the potential to affect all ICHD patients.</p> <p>Findings include:</p> <p>1. During an observation on the in-center hemodialysis treatment floor on 2/20/24 at 8:59 AM, two unlabeled 3 milliliter (ml) syringes filled with a clear solution were observed on the counter of a supply station.</p> <p>During an interview with PCT 7 on 2/20/24 at 9:54</p>	V 0401	<p>the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p> <p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on policies listed below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <p style="padding-left: 40px;">Medication Preparation and Administration version 9 General Cleanliness and Infection Control Guidelines version 6</p>	03/22/2024

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	<p>AM, the technician reported he/she had previously drawn up Heparin into the 2 unlabeled syringes for 2 patients and had stored them at the supply station until needed. PCT 7 stated he/she "knew" which patient was to be given which Heparin syringe.</p> <p>During an interview with Administrator and Clinic Manager 2 on 2/20/24 beginning at 4:40 PM, the administrative staff reported medication prepared for a later administration should be labeled and kept in a locked compartment.</p> <p>2. During an observation on the ICHD treatment floor on 2/21/24 at 8:24 AM, three supply boxes and 1 tub filled with saline bags were observed in the middle of the treatment floor by Stations #7 and #8. Two of the supply boxes were unopened and sitting on a cart. The tub filled with saline bags and 1 empty supply box were sitting on the treatment floor. Facility staff and patients were observed having to walk around the boxes and tub.</p>		<p>Emphasis was placed on:</p> <p><u>-All medications in syringes not being administered immediately shall be labeled appropriately with the name of the medication, route, dose, name of patient, date, time, and initials of the person who prepared the medication.</u></p> <p><u>-All medications will be kept in a locked cabinet except when in use.</u></p> <p><u>-All areas must be kept clean and organized</u>, including but not limited to the treatment area, water/supply room and offices. <u>Walkways must be kept clear of debris and free of clutter.</u></p> <p>On 3/7/24, the Clinical Manager implemented daily audits with focus on ensuring all medication not immediately given are labeled and secured, as well as, ensuring the treatment area remains free of debris and clutter and walkways are kept clear utilizing the Clinic Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Audits will continue daily until receipt of the Statement of Deficiencies and then will be re-evaluated at that time.</p> <p>Effective 3/21/24, Clinical Manager will conduct daily audits with focus on ensuring all medication not immediately given will be labeled</p>	

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			<p>and secured, as well as ensuring the treatment area remains free of debris and clutter and walkways are kept clear utilizing Clinic Audit Tool for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to</p>	

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V 0450 Bldg. 00	494.70 CFC-PATIENTS- RIGHTS Based on observation, record review, and interview, the dialysis facility failed to protect the patients' right to be free from verbal abuse from facility staff (See V452), failed to ensure the patient's right to privacy during verbal interactions between staff was maintained (See V454), failed to ensure the patient's clinical documents remained confidential and private on the in-center hemodialysis (ICHD) treatment floor (See V455), failed to protect the patients' rights and ensure the patient received his/her dialysis prescription as ordered (See V463), failed to investigate and document resolution of patient grievances according to facility policy (See V465), failed to ensure all patients remained free from retaliation for filing a complaint with the State Agency (SA) and/or with the facility (See V467),	V 0450	develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 3/22/24. The Governing Body of this facility acknowledges its responsibility to ensure the dialysis facility protects patients' right to be free from verbal abuse from facility staff, ensure the patient's right to privacy during verbal interactions with staff, to ensure patients' clinical documents remain confidential and private, to ensure the patients' receive the prescribed dialysis treatment, as ordered, to ensure patient grievances contain complete and thorough documentation through to resolution, to ensure patient's remain free from retaliation for filing a compliant with the State	03/22/2024

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	<p>and failed to ensure policies and procedures were followed when they involuntarily discharged a patient (See V469).</p> <p>The Administrator and Clinic Manager were notified on 02/19/24 at 3:22 PM of an Immediate Jeopardy at 42 CFR 494.70 Patients' Rights. The Immediate Jeopardy was identified, beginning on 02/09/2024. The immediacy was not abated prior to survey exit on 02/22/24.</p> <p>The scope and severity of these systemic problems resulted in the ESRD facility failing to protect and promote Patients' Rights, which resulted in Fresenius Medical Care Gary was found to be out of compliance with 42 CFR 494.70 Patients' Rights.</p>		<p>Agency and/or the facility, and to ensure the facility policy and procedure for Involuntary Discharge is followed.</p> <p>As such, the Governing Body held a conference call on 2/26/24 to review the information provided by the surveyors during this survey and actively participate in the development of the Plan of Correction. The Governing Body has committed to meet weekly to review the status of the Plan of Correction until all issues are resolved and the facility is back in compliance.</p> <p>The Governing Body met again on 3/18/24, to review the Statement of Deficiencies and develop the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution.</p> <p>The Governing Body began meeting weekly beginning 2/26/24 to review the results of the progress on the Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The Governing Body will determine when the frequency of these meetings may be reduced to the regular quarterly schedule. Effective immediately:</p> <p>-The Clinical Manager will</p>	

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			<p>analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee.</p> <ul style="list-style-type: none"> -A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. -The QAI Committee is responsible for reviewing and evaluating the Plan of Correction to ensure it is effective and providing resolution of the issues. -The Facility Administrator will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. -The Governing Body, at its meeting of 2/26/24, designated the Facility Administrator to serve as Plan of Correction Monitor and provide additional oversight. They will participate in QAPI and Governing Body meetings. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement of Deficiency through to resolution as well as ensure the Governance of the Facility is presented current and complete data to enhance their governance oversight role. 	

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V 0452 Bldg. 00	<p>494.70(a)(1) PR-RESPECT & DIGNITY The patient has the right to-</p> <p>(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</p> <p>Based on observation, record review, and interview, the dialysis facility failed to protect the patients' right to be free from verbal abuse from facility staff for 2 of 2 reported and/or observed incidents of verbal abuse towards in-center hemodialysis (ICHD) patients by facility staff (Patients #3 and 21) and 1 of 1 discharged clinical record reviewed (Patient # 8) who transferred to another clinic within the 14 days prior to complaint survey.</p>	V 0452	<p>Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction, and oversight and the QAI Committees ongoing monitoring of facility activities. These are available for review at the facility.</p> <p>The responses provided for V 452, V 454, V 455, V 463, V 465, V 467, and V 469 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies cited within this Condition are corrected to ensure ongoing compliance.</p> <p>On 3/1/24, The Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on the policy below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p>	03/22/2024

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	<p>Findings include:</p> <p>1. The policy titled "Patient Rights and Responsibilities," dated 4/04/12, indicated the facility "must protect and provide for the exercise" of the patient's rights. The policy indicated the patient's rights included but was not limited to "respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs"</p> <p>2. During an interview with Patient #3 on 2/14/24 beginning at 9:09 AM, Patient reported that on 02/09/24, Patient Care Technician (PCT) 1 scratched and slapped him/her while setting up Patient's dialysis treatment. Patient reported he/she had previously filed a complaint with the facility against PCT 1, so the technician was only supposed to "push the buttons" on Patient's dialysis machine and was not to provide direct patient care, however on 2/09/24, the facility was short-staffed and PCT 1 had to set up Patient's dialysis treatment. Administrator came to Patient's chairside shortly after to discuss the alleged incident. Patient #3 reported during his/her conversation with Administrator, Patient asked how Administrator would like if their family member was being assaulted? Patient #3 reported Administrator became angry at Patient's comment regarding his/her family member and began yelling at Patient. Patient reported he/she was "in fear of my life" and had become anxious when seeing Administator on the treatment floor on 02/09/24.</p> <p>The review of an audio recording of Patient #3 and Administrator's interaction on 02/09/24 evidenced during the interaction, Patient #3 stated PCT 1 wanted to "beat the garbage out of me ... we could have had a fight. I've had people assault me before." Administrator responded, "And you</p>		<p>-Documenting Progress Notes, Transfers, Transplants, Discharges and Order Review version 6</p> <p>Emphasis was placed on: The nurse or designee will complete the discharge summary assessment in eCC for each discharged patient (permanent and transient) as soon as reasonably possible and within 30 days of a patient being discharged from the facility. The nurse will provide the necessary information to complete the discharge summary assessment.</p> <p>On 2/20/24, the Clinical Manager and Manager of Social Work held a staff meeting to provide education and to reinforce the expectations and responsibilities of the facility staff on the policies below.</p> <p>On 3/18/24 & 3/19/24, after receipt of the Statement of Deficiencies, the Social Work Managers met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <p>Patient Rights and Responsibilities List version 3 Patient Rights and Responsibilities Procedure version 2</p>	

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	<p>beat them up." Patient denied saying he/she had beat anyone up and patient hoped "somebody beat [the Administrator's family member] up like [PCT 1]'s doing." Administrator stated his/her family member had died and Patient #3 responded stating "And maybe that's why." Administrator was heard yelling "So my [family member] is dead and [Patient #3] thinks [the family member]'s dead because [the family member] got beat up. You have lost your mind." Additional staff members could be heard coming to the chairside and telling Administrator to walk away.</p> <p>During an interview with Employee E on 02/14/24 beginning at 12:31 PM, the employee reported he/she was on the treatment floor during Patient #3 and Administrator's interaction on 02/09/24. The employee reported the Administrator "got loud" when speaking with Patient #3.</p> <p>During an interview with Administrator on 02/19/24 at 3:27 PM, the employee reported an audio recording on the treatment floor violated the policies and procedures Patients agree to abide by when they are admitted to the facility. The administrator indicated he/she did not yell at Patient #3, rather he/she was talking loudly because Administrator wanted everyone to hear what he/she was saying as Patient #3 "has done this many times."</p> <p>3. During an observation on the ICHD treatment floor on 2/22/24 beginning at 12:45 PM, PCT 10 was observed interacting with Patient #21 while Patient was receiving ICHD. Patient raised his/her legs and the technician told Patient to put their legs down. When Patient asked why, PCT 10 stated "because you not that sexy." Patient attempted to get out of the treatment chair several times saying he/she wanted something to eat.</p>		<p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -All facilities should post the Patient and Staff Partnership Poster where it is easily visible and accessible to patients. -Each patient or his/her representative will be provided a copy of the FMCNA Patient Rights brochure and the FMCNA Patient Responsibilities brochures within the first six (6) dialysis treatments in the facility as required per policy. -A Social Worker or Nurse should review specific information related to facility policies that are contained in the FMCNA Patient Rights and Responsibilities brochures with a patient or his or her representative. This should occur when the information is given or shortly thereafter, and discussed or reviewed over a period, to ensure understanding. -The patient or his/her representative is presented with an Acknowledgement of Receipt of FMCNA Patient Rights and Responsibilities to sign when information is provided the first time. -Document in the medical record each time patient rights information is provided or discussed with patients and/or their representative. -<u>Patients have the right to:</u> -Information that is easy to understand. 	

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE GARY	STREET ADDRESS, CITY, STATE, ZIP COD 3290 GRANT ST GARY, IN 46408
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	<p>PCT 10 told Patient not to get out of their chair and then said "[Patient #21] if I have to ..."</p> <p>Patient interrupted the technician, asking what the employee was going to do? PCT responded stating "you know." At 12:59 PM, PCT 10 told Patient #21 "you have acted like a small child and I don't like it ... you have proven you don't know how to act." The technician informed Patient that his/her extended care facility may not allow Patient #21 to return "because of how you acted today." PCT 10 told Patient #21 he/she would be glad when Patient left for the day. Patient #10 told the technician he/she was being starved "to death;" the technician was observed laughing.</p> <p>During an observation on the ICHD treatment floor on 2/22/24 beginning at 2:45 PM, PCT 10 was observed discontinuing Patient #21's ICHD treatment. Patient #21 asked the technician if he/she was going home. PCT 10 responded he/she didn't know if Patient was going home "because [Patient #21] have acted just so terribly today ... like a child ... I don't appreciate it ... You might never get [to the extended care facility]." PCT 10 and Patient #21's conversation could be heard on the other side of the ICHD treatment floor. RNs 4 and 5 and PCTs 4, 5, and 8 were present on the treatment floor during the observation but did not intervene.</p> <p>During an interview with RN 5 on 02/22/24 beginning at 2:35 PM, the nurse reported Patient #21 was more "aggravated" than his/her baseline. The nurse reported the facility typically had snacks available for Patient #21 "to keep the peace," however this was not available on 02/22/24. RN 5 reviewed Patient #21's medical record and indicated Patient had a history of anxiety and panic disorder.</p>		<p><u>·Care that is respectful.</u></p> <p><u>·Be protected from discrimination and or harassment based on race, color, national origin, sexual orientation, gender identity, disability, age, sex and religion.</u></p> <p><u>·Be treated with dignity, consideration, respect and full recognition of your individuality and personal needs. This includes sensitivity to your psychological needs and ability to cope with ESRD.</u></p> <p>·Say "no" and report staff that ask you to engage in personal or financial relationships, without fear of retaliation.</p> <p>·Help make decisions about your care.</p> <p>·Privacy and Confidentiality</p> <p>·Clear information about facility policies.</p> <p>·Make a complaint and receive a response.</p> <p>On 3/4/24, the Clinical Manager implemented weekly audits of the Admission/Discharge Report for a list of patients discharged from the facility to ensure a discharge summary assessment was completed for each discharge and to include the reason for discharge.</p> <p>Effective 3/21/24, Clinical Manager will conduct weekly audits of the Admission/Discharge Report for a list of patients discharged from the</p>	

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	<p>A review of Patient #21's medical record indicated Patient was currently taking Aricept and Memantine (medications used to treat dementia) as well as Clonazepam for anxiety.</p> <p>4. An agency document titled "Admission/Discharge" report, received on 2/16/24, evidenced patient #8 was transferred to another facility on 02/05/24.</p> <p>5. The clinical record for Patient #8 evidenced a discharge summary dated 02/05/24; the record failed to evidence why Patient #8 was discharged from the facility.</p> <p>During a phone interview on 02/16/24 at 10:42 AM, Patient #8 indicated there was always loud music and yelling. The staff were very blasé and acted like it was not a medical facility. Patient #8 indicated the staff didn't care about Patients, it was ghetto. Staff would hang their lab coats around their neck and then they would brush against you with the sleeves of their street clothes. Patient #8 indicated how were they to know if the staff had a dog licking all over their sleeve or where the sleeve had previously touched. Patient #8 indicated the nurses were as bad as the PCTs. Patient #8 indicated staff would go person to person with the same gloves, put a glove on one finger to use the machine, or hold their access site. Patient #8 indicated they could not take it, indicated when they would complain about the music and the unsanitary practices, staff indicated Patient #8 complained too much. Patient #8 stated "My rights were violated there," indicated if they said something to staff about what they didn't like, the staff would get snotty. Patient #8 indicated he/she had the right to say how they felt, but staff did not listen. Patient #8 indicated when he/she said something about loud</p>		<p>facility and will ensure a discharge summary assessment is completed for each discharge and includes the reason for discharge for 4 weeks and then will continue monthly. Documentation of patients discharged from the clinic as well as reason for discharge will be reviewed at the monthly QAI meeting with documentation noted in the meeting minutes in eQUIP.</p> <p>The Clinic Manager will be responsible for observing staff/patient interactions by performing a daily observation of the treatment floor before, during and after patient treatments for 2 weeks and then weekly times 4 weeks, beginning 2/21/24. Any inappropriate behaviors identified, including, but not limited to, verbal abuse, whether staff or patient, will be immediately investigated to determine the appropriate course of action, and with documentation noted in the employee personnel file or in the patient medical record.</p> <p>Effective 3/21/24, Clinic Manager will be responsible for observing staff/patient interactions by performing a daily observation of the treatment floor before, during and after patient treatments for 2 weeks and then weekly for an additional 4 weeks. Any inappropriate behaviors identified,</p>	

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	<p>music, they would say what you don't like music. Patient #8 indicated Staff would play on their phone more than a 17-year-old and not pay attention to Patients. Patient #8 indicated on one visit, they had to yell over the music to notify staff, that their access site had started to bleed, as no one was paying attention. Patient #8 indicated they were told all they did was complain. Patient #8 stated, "I didn't feel I should have to go through that," Patient #8 indicated they showed up for their last dialysis treatment and staff told Patient #8 they were not to be there. Patient #8 indicated he/she were scheduled, the PCT left and returned and then said, "Fine, they said you can be here."</p> <p>During an interview on 02/16/2024 at 2:40 PM, Clinic Manager 2 indicated from his/her understanding Patient #8 transferred to another unit because there were Patients around Patient #8 who would play music during treatment, and Patient #8 was upset because it was too loud. The Clinic Manager indicated staff would sometimes play music during the holidays and on Friday afternoons, but it was at an acceptable level, or the Clinic Manager would have staff turn it down. Clinic Manager 2 indicated Patient #8 did not express this to him/her, but it was the Clinic Manager's understanding of why Patient #8 left.</p>		<p>including, but not limited to, verbal abuse, whether staff or patient, will be immediately investigated to determine the appropriate course of action, and with documentation noted in the employee personnel file or in the patient medical record. The Governing Body will determine on-going frequency of the observations based on behaviors identified/observed. Documentation of findings will be discussed in QAI and noted in the meeting minutes.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause</p>		

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V 0454 Bldg. 00	<p>494.70(a)(3) PR-PRIVACY & CONFIDENTIALITY-TREATMENT The patient has the right to-</p> <p>(3) Privacy and confidentiality in all aspects of treatment;</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure the patient's right to privacy during verbal interactions between staff was maintained for 1 of 1 patient observed with low blood pressure on the treatment floor (Patient #22).</p> <p>Findings include:</p> <p>The review of facility policy titled "Patient Rights and Responsibilities," dated 4/04/12, indicated the</p>	V 0454	<p>analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p> <p>On 2/20/24, the Clinical Manager and Manager of Social Work held a staff meeting to provide education and to reinforce the expectations and responsibilities of the facility staff on the policies below.</p> <p>On 3/18/24 & 3/19/24, after receipt of the Statement of Deficiencies, the Social Work Managers met with staff to reeducate and</p>	03/22/2024

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	<p>patient had the right to "privacy and confidentiality in all aspects of treatment."</p> <p>During an observation on 2/20/24 at 9:03 AM, Patient Care Technician (PCT) 2 was at Station #1 with Patient #22. PCT 2 called across the room to Registered Nurse (RN) 4 and indicated Patient #22 blood pressure was 98/56. PCT 2 failed to keep the confidentiality of Patient #22's treatment.</p> <p>During an interview on 2/20/2023 at 10:00 AM, PCT 2 indicated he/she should have gone to the nurse and not called out the blood pressure from across the room.</p>		<p>reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> -Patient Rights and Responsibilities List version 3 -Patient Rights and Responsibilities Procedure version 2 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -All facilities should post the Patient and Staff Partnership Poster where it is easily visible and accessible to patients. -Each patient or his/her representative will be provided a copy of the FMCNA Patient Rights brochure and the FMCNA Patient Responsibilities brochures within the first six (6) dialysis treatments in the facility. -A Social Worker or Nurse should review specific information related to facility policies that are contained in the FMCNA Patient Rights and Responsibilities brochures with a patient or his or her representative. This should occur when the information is given or shortly thereafter, and discussed or reviewed over a period, to ensure understanding. -The patient or his/her representative is presented with an Acknowledgement of Receipt of FMCNA Patient Rights and Responsibilities to sign when information is provided the first time. 	

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			<ul style="list-style-type: none"> ·Document in the medical record each time patient rights information is provided or discussed with patients and/or their representative. ·<u>Patients have the right to:</u> <ul style="list-style-type: none"> ·Information that is easy to understand. ·Care that is respectful. ·Help make decisions about your care. ·<u>Privacy and Confidentiality</u> <ul style="list-style-type: none"> ·<u>Privacy and confidentiality in all aspects of treatment.</u> This includes the right to privately discuss your condition as well as the right to privacy during activities that may require the exposure of body parts while in the dialysis facility. Privacy screens, curtains, or blankets that do not cover your face or access may be used to provide privacy. <ul style="list-style-type: none"> ·Privacy and confidentiality in your personal medical records. ·Clear information about facility policies. ·Make a complaint and receive a response. <p>The Clinic Manager will be responsible for observing staff/patient interactions by performing a daily observation of the treatment floor before, during and after patient treatments for 2 weeks and then weekly times 4 weeks, beginning 2/21/24. Any inappropriate behaviors identified</p>	

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			<p>will be immediately addressed, the appropriate course of action, and with documentation noted in the employee personnel file.</p> <p>Effective 3/21/24, Clinic Manager will be responsible for observing staff/patient interactions by performing a daily observation of the treatment floor before, during and after patient treatments for 2 weeks and then weekly for an additional 4 weeks. Any inappropriate behaviors identified, including, but not limited to, violation of patient's right to privacy and confidentiality of a patient's treatment will be immediately addressed, the appropriate course of action implemented, and with documentation noted in the employee personnel file. The Governing Body will determine on-going frequency of the observations based on behaviors identified/observed. Documentation of findings will be discussed in QAI and noted in the meeting minutes.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of</p>	

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V 0455 Bldg. 00	494.70(a)(4) PR-PRIVACY & CONFIDENTIALITY-RECORDS The patient has the right to-		<p>Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p>	

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	<p>(4) Privacy and confidentiality in personal medical records;</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure the patient's clinical documents remained confidential and private on the in-center hemodialysis (ICHD) treatment floor for 3 of 4 days of ICHD observations, which had the potential to affect all ICHD facility patients.</p> <p>Findings include:</p> <p>1. During an observation of the in-center treatment floor on 2/14/24 beginning at 2:55 PM, an ICHD treatment schedule for 2/14/24 with patients' full names was observed in the trash.</p> <p>During an interview with Administrator on 2/14/24 beginning at 3:05 PM, Administrator reported documents with protected health information (PHI), including treatment schedules, should be placed into the facility's shredder bin.</p> <p>2. During an observation of the ICHD treatment floor on 2/19/24 at 11:44 AM, Registered Nurse (RN) 4 was observed reviewing Patient #3's medical record on a computer at the nurse's station. RN 4 left the nurse's station to speak with the patient in Station #3. The nurse failed to lock the computer prior to leaving the nurse's station, leaving Patient #3's medical record open on the computer screen.</p> <p>3. During an observation on 2/20/24 at 9:00 AM, a clipboard was observed on the ledge of the nursing station. The clipboard contained an early termination form for Patient #23. This form included Patient #23 name, the date 2/20/2024, and the time 8:40 AM. The agency failed to keep</p>	V 0455	<p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on policies listed below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <p style="text-align: center;">HIPAA Privacy Policy and Procedures COR-ISO-024 Medical Record Documentation Standards version 4</p> <p>On 2/20/24, the Clinical Manager and Manager of Social Work held a staff meeting to provide education and to reinforce the expectations and responsibilities of the facility staff on the policies below.</p> <p>On 3/18/24 & 3/19/24, after receipt of the Statement of Deficiencies, the Social Work Managers met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p>	03/22/2024

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	<p>Patient #22 medical record information confidential.</p> <p>During an interview on 2/20/24 at 9:05 AM, RN 5 indicated the form should not have been left on the counter. The form and clipboard should have been put away or at least kept face down on the desk until someone could take care of it.</p>		<ul style="list-style-type: none"> ·Patient Rights and Responsibilities List version 3 ·Patient Rights and Responsibilities Procedure version 2 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> ·Paper PHI should be secured, and access should be limited based on job duties. ·Paper PHI should be properly discarded in a container marked for shredding. ·Storage of electronic PHI is limited to those who require access to perform their job duties. <p>All patients' medical records will be maintained in accordance with accepted professional standards and practices, and in compliance with state law.</p> <p><u>Patients have the right to:</u></p> <ul style="list-style-type: none"> Information that is easy to understand. Care that is respectful. Help make decisions about your care. <p><u>Privacy and Confidentiality</u></p> <p>Privacy and confidentiality in all aspects of treatment. This includes the right to privately discuss your condition as well as the right to privacy during activities that may require the exposure of body parts while in the dialysis facility. Privacy screens, curtains, or blankets that do not cover your face or access may be used to provide privacy.</p>	

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			<p><u>Privacy and confidentiality in your personal medical records.</u></p> <p>Clear information about facility policies</p> <p>The Clinic Manager will be responsible for observing staff/patient interactions by performing a daily observation of the treatment floor before, during and after patient treatments for 2 weeks and then weekly times 4 weeks, beginning 2/21/24. Any inappropriate behaviors identified (i.e. patient treatment schedule in the trash, unlocked/unattended computer screen with open medical record, AMA form left on clipboard) will be immediately addressed, the appropriate course of action implemented, and with documentation noted in the employee personnel file.</p> <p>Effective 3/21/24, Clinic Manager will be responsible for observing staff/patient interactions by performing a daily observation of the treatment floor before, during and after patient treatments for 2 weeks and then weekly for an additional 4 weeks. Any inappropriate behaviors identified, including, but not limited to, violation of patient's right to privacy and confidentiality of a patient's treatment will be immediately addressed (i.e. patient treatment schedule in the trash, unlocked/unattended computer screen with open</p>	

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE GARY	STREET ADDRESS, CITY, STATE, ZIP COD 3290 GRANT ST GARY, IN 46408
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			<p>medical record, AMA form left on clipboard), the appropriate course of action implemented, and with documentation noted in the employee personnel file. The Governing Body will determine on-going frequency of the observations based on behaviors identified/observed.</p> <p>Documentation of findings will be discussed in QAI and noted in the meeting minutes.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction.</p>	

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V 0463 Bldg. 00	<p>494.70(a)(12) PR-RECEIVE SERVICES OUTLINED IN POC The patient has the right to-</p> <p>(12) Receive the necessary services outlined in the patient plan of care described in §494.90;</p> <p>Based on record review and interview, the dialysis facility failed to protect the patients' rights specific to ensuring the patient received his/her dialysis prescription as ordered for 1 of 1 records reviewed of a patient whose in-center hemodialysis (ICHD) treatment was shortened without the patient's consent (Patient #3).</p> <p>Findings include:</p> <p>During an interview with Patient #3 on 2/14/24 beginning at 9:09 AM, Patient reported that on 02/09/24, Patient Care Technician (PCT) 1</p>	V 0463	<p>The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p> <p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on policies listed below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities</p>	03/22/2024

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	<p>scratched and slapped him/her while setting up Patient's dialysis treatment. Patient reported he/she had previously filed a complaint with the facility against PCT 1, so the technician was only supposed to "push the buttons" on the patient's dialysis machine and not provide direct patient care, however on 2/09/24, the facility was short-staffed and PCT 1 had to set up the patient's dialysis treatment. Administrator came to Patient's chairside shortly after to discuss the alleged incident. Patient #3 reported during his/her conversation with Administrator, the employee denied the alleged incident between Patient #3 and PCT 1 occurred and Patient asked how Administrator would like if their family member was being assaulted? Patient #3 reported Administrator became angry at Patient's comment regarding his/her family member and began to yell at Patient. While leaving the treatment floor, Administrator yelled "take [him/her] off [the dialysis treatment]." Patient #3 reported after his/her interaction with Administrator, the facility staff ended his/her treatment 2 hours prior to the ordered end time.</p> <p>The review of an audio recording of Patient #3 and Administrator's interaction on 02/09/24 evidenced during the interaction, Patient #3 stated PCT 1 wanted to "beat the garbage out of me ... we could have had a fight. I've had people assault me before." Administrator responded, "And you beat them up." Patient denied saying he/she had beat anyone up and patient hoped "somebody beat [the Administrator's family member] up like [PCT 1]'s doing." Administrator stated his/her family member was dead and Patient #3 responded stating "And maybe that's why." Administrator was heard yelling "So my [family member] is dead and [Patient #3] thinks [the family member]'s dead because [the family member] got beat up. You</p>		<p>of the facility staff on policies:</p> <ul style="list-style-type: none"> -Nursing Supervision and Delegation version 6 -Patient Assessment and Monitoring version 4 <p>On 2/20/24, the Clinical Manager and Manager of Social Work held a staff meeting to provide education and to reinforce the expectations and responsibilities of the facility staff on the policies below.</p> <p>On 3/18/24 & 3/19/24, after receipt of the Statement of Deficiencies, the Social Work Managers met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> -Patient Rights and Responsibilities List version 3 -Patient Rights and Responsibilities Procedure version 2 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -The staff member who collects information pre, post and during treatment will document their findings. Any observed changes or abnormal findings in the patient's condition or vascular access, changes reported by the patient, recent hospitalizations, or other medical procedures (ex. dental procedures) must be reported to 	

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	<p>have lost your mind." Additional staff members could be heard coming to the chairside and telling Administrator to walk away. Administrator could then be heard yelling in the distance "take [Patient #3] off [his/her dialysis treatment]."</p> <p>During an interview with Employee H on 02/14/24 beginning at 11:24 AM, the employee reported on 02/9/24, a police officer and ambulance came to the facility after the alleged assault by PCT 1 against Patient #3. Employee H reported Patient was "stable," so the police officer sent the ambulance away prior to the EMT assessing Patient #3. The employee also reported Patient #3 received his/her full treatment on 02/09/24.</p> <p>The review of Patient #3's medical record evidenced Patient's treatment on 02/09/24 ended at 8:55 AM, which was 1 hour 37 minutes prior to the ordered end of treatment. Employee H documented Patient's dialysis prescription, including Estimated Dry Weight (EDW, physician-ordered goal weight patients are to be at the end of dialysis treatment) was not achieved "due to [Patient #3's] inappropriate behavior." Patient #3's post-dialysis blood pressure was 165/103, heart rate was 113, and weight was 95.2 kilograms (kg). The record indicated Patient's EDW was 91.0 kg, a difference of 4.2 kg.</p> <p>During an interview with Medical Director on 2/14/24 beginning at 1:25 PM, the physician reported he/she was not aware Patient #3's treatment ended early on 02/09/24.</p> <p>During an interview with Administrator on 02/14/24 beginning at 3:54 PM, Administrator reported on 02/09/24, as he/she was leaving the treatment floor after speaking with Patient #3, Administrator advised facility staff to end Patient</p>		<p>the registered nurse who will assess the patient.</p> <ul style="list-style-type: none"> · <u>The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.</u> · <u>Prior to discharge, the RN must review the treatment record to:</u> <ul style="list-style-type: none"> · <u>Confirm patient is stable for discharge.</u> · <u>Identify any process that could have resulted in the patient experiencing a safety event or near miss.</u> · <u>The record must be reviewed for:</u> <ul style="list-style-type: none"> · <u>Slow/fast/irregular heart rate</u> · <u>Low or high blood pressures</u> · <u>Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight</u> · Heart rate <60 or >100 addressed by the registered nurse with documentation present · Blood pressures < 100 systolic or greater than 180 systolic addressed by the registered nurse with or documentation present. · Reported fall, and if heparin was held and MD notified. · Correct dialysate prescription was delivered. · <u>Patients have the right to:</u> <ul style="list-style-type: none"> · Information that is easy to understand. · <u>Care that is respectful.</u> · <u>Be protected from discrimination and or harassment</u> 	

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	<p>#3's treatment early due to Patient saying he/she "should have" hit PCT 1.</p> <p>During an interview with Employee G on 02/15/24 beginning at 1:00 PM, the employee reported on 02/09/24, Patient #3 stated he/she felt like they were going to have a stroke, so Employee G spoke with Employee H and was advised to end Patient's treatment early. Administrator then came to Patient #3's chairside to discuss the earlier alleged incident with PCT 1, so Employee H waited until the conversation was over to begin disconnecting Patient #3 from their treatment.</p> <p>The review of Patient #3's medical record failed to evidence Patient reported signs or symptoms of a stroke (headache, confusion, slurred speech, etc) at any point during his/her treatment on 2/09/24.</p> <p>During a follow-up interview with Patient #3 on 02/16/24 beginning at 10:55 AM, Patient reported on 02/09/24, after the alleged assault by PCT 1, Patient #3 asked to speak with a nurse because he/she felt anxious and his/her blood pressure was elevated. Patient #3 stated he/she told staff he/she was concerned he/she might have a stroke, but staff told her to take deep breaths and to try to stay on treatment. Patient #3 reported he/she had calmed down and was feeling ok until his/her interaction with Administrator, after which he/she was "shaky." Patient #3 reported he/she did not voice any concerns and/or symptoms of a stroke after their interaction with Administrator.</p> <p>The review of the facility's adverse event log between 2/14/23 - 2/14/24 evidenced 2 adverse events involving Patient #3 dated 02/09/24. The log included:</p> <p>a. An adverse event for "hemolysis" documented</p>		<p><u>based on race, color, national origin, sexual orientation, gender identity, disability, age, sex and religion.</u></p> <p><u>·Be treated with dignity, consideration, respect and full recognition of your individuality and personal needs. This includes sensitivity to your psychological needs and ability to cope with ESRD.</u></p> <p>·Say "no" and report staff that ask you to engage in personal or financial relationships, without fear of retaliation.</p> <p>·Help make decisions about your care.</p> <p>·Privacy and Confidentiality</p> <p>·Clear information about facility policies.</p> <p>·Make a complaint and receive a response.</p> <p>Effective 3/6/24, the Clinical Manager or designee will conduct audits on 10 treatment sheets daily, alternating shifts, with focus on ensuring patients receive their dialysis prescription as ordered utilizing Treatment Sheet Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Treatment sheet audits will continue daily until receipt of the Statement of Deficiencies is received and re-evaluated at that time.</p>	

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	<p>by PCT 1 at 9:19 AM. The event report indicated after performing Patient #3's CVC care, the technician secured Patient #3's CVC lines to Patient's left shoulder. Patient began to pull the lines and "direct where [he/she] would like to place the tape." PCT 1 documented he/she asked Patient to loosen the arterial line "to prevent the machine from alarming due to noticing restriction." Patient #3 "became argumentative," telling the technician "that is not the reason for the machine alarming," and asking the technician to "just do what [he/she] was asked to do." PCT 1 documented he/she placed tape where Patient requested and Patient "yelled out ... I know you just didn't hit me! Back away from me!" The event report indicated the technician [sic] "confessed that [he/she] did not hit [Patient #3]," left Patient's station, and informed the facility's management. PCT 1 documented Patient #3 "called the police to make a report."</p> <p>Review of Patient #3's clinical record evidenced Patient's dialysis treatment began on 2/09/24 at 7:04 AM. Review of the police report filed regarding the police investigation of PCT 1's alleged assault against Patient indicated the assault was initially reported to the police at 7:09 AM. The police officer's last radio log was at 8:16 AM to report the investigation was complete. Patient #3's treatment floor sheet indicated the patient's treatment ended at 8:57 AM, which was after Patient and Administrator spoke.</p> <p>b. An adverse event for "Dialysis Weight/[Ultrafiltration] Goal Variance" documented by Administrator at 3:11 PM. The event report indicated Patient #3 "had a behavioral occurrence while at treatment ... [Patient] had an outburst, called the police alleging that [he/she] was assaulted by a PCT. [Patient #3] threatened</p>		<p>Effective 3/21/24, Clinical Manager or designee will conduct audits on 10 treatment sheets daily, alternating shifts, with focus on ensuring patients receive their dialysis prescription as ordered utilizing Treatment Sheet Audit Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible</p>	

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V 0465 Bldg. 00	<p>stating that [he/she] 'should've fight [sic] [the technician] back.' [Patient #3's] treatment was immediately ended."</p> <p>494.70(a)(14) PR-INFORMED OF INTERNAL GRIEVANCE PROCESS The patient has the right to-</p> <p>(14) Be informed of the facility's internal grievance process;</p> <p>Based on record review and interview, the dialysis facility failed to investigate and document resolution of patient grievances according to facility policy for 2 of 4 patients who reported they filed grievances with the facility (Patient #3 and 8).</p> <p>Findings include:</p>	V 0465	<p>for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p> <p>On 3/1/24, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on the below policy.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the</p>	03/22/2024

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	<p>1. The review of facility policy titled "Patient Grievance," dated 1/02/14, indicated all patients had the right to file a grievance at any time and could be filed written or verbally. The policy indicated the social worker's responsibility for grievances included "assisting in assessing and resolving patient grievances as appropriate" and the clinic manager and/or administrator was to meet with the complainant "within 5 days to discuss the grievance, resolve it as quickly as possible, and provide periodic updates to the patient."</p> <p>2. The review of facility's grievance log indicated on 8/09/23, Patient #3 filed a verbal grievance with MSW 1. The log indicated Patient wanted to file a grievance against Registered Nurse (RN) 1 because the nurse administered fluid when Patient's blood pressure dropped and the Patient thought he/she was becoming "ill" because of the additional fluid. The log indicated Patient #3 "also had complaints about [his/her] dry weight" and reported when he/she requested to speak with Medical Director, the facility nurses refused to contact the physician. The grievance log indicated MSW 1 documented a "late entry" that he/she spoke with Patient #3 and Patient reported "nothing is changed." MSW 1 documented Patient "did not want to elaborate." The grievance log failed to evidence a documented resolution to the patient's grievance, however the grievance was marked as "resolved" on 9/15/23.</p> <p>The review of Patient #3's medical record evidenced a Progress Note documented by MSW 1 on 8/9/23. The note indicated MSW 1 spoke with Patient at his/her chairside and Patient reported he/she wanted to file the above grievance. MSW 1 documented he/she educated Patient on "chain of command" for grievance</p>		<p>expectations and responsibilities of the facility staff on policies:</p> <p>Documenting Progress Notes, Transfers, Transplants, Discharges and Order Review version 6</p> <p>On 2/20/24, the Clinical Manager and Manager of Social Work held a staff meeting to provide education and to reinforce the expectations and responsibilities of the facility staff on the policies below.</p> <p>On 3/18/24 & 3/19/24, after receipt of the Statement of Deficiencies, the Social Work Managers met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <p>Patient Grievance version 3 Patient Grievance Procedure version 3</p> <p>Emphasis was placed on: The nurse will complete the discharge summary assessment, <u>inclusive of discharge reason</u>, in eCC for each discharged patient (permanent and transient) as soon as reasonably possible and within 30 days of a patient being discharged from the facility. The nurse will provide the necessary information to complete the discharge summary assessment. <u>When a patient or patient</u></p>		

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	<p>procedures and discussed the situation with Administrator. The record indicated the next social work note was dated 10/23/23, within which MSW 1 documented Clinic Manager 2 reported Patient #3 was not listening to staff "regarding [his/her] treatment" and was not adhering to treatment orders.</p> <p>During an interview with MSW 1 on 2/15/24 beginning at 11:27 AM, the social worker stated he/she reported Patient #3's complaint to Administrator. MSW 1 could not recall when he/she followed up with Patient regarding his/her complaint and stated the patient declined to elaborate on how his/her treatments were going, so the social worker marked the grievance as resolved. The social worker reported the facility attempted to hold a meeting with Patient #3 in either October or December 2023 in part due to the patient's non-adherence to his/her ordered treatment, but Patient did not come to the meeting.</p> <p>Patient #3's record indicated the patient was given notification of an involuntary discharge on 2/12/24 with an effective date of 3/12/24. The listed reasons for discharge included the facility could no longer meet the patient's needs.</p> <p>3. A review of the facility's grievance log for 2/14/23 - 2/14/24 indicated on 12/13/23, Patient #8 filed a verbal grievance with MSW 1. The log indicated Patient was "very agitated," reported he/she "can't get any rest due to the noise in the clinic ... the PCT's 'talk to much' [sic] ... music was playing and [Patient #8] did not understand why [he/she] has to listen to music" The log indicated Patient's family member had suggested noise-cancelling headphones, but Patient could not afford them. MSW 1 spoke with Patient #8 to follow-up regarding the grievance and Patient</p>		<p><u>representative has a grievance:</u></p> <p><u>FKC Staff promptly acknowledges and reports all patient grievances to the Nurse in Charge (or Team Leader) as soon as possible.</u></p> <p><u>The Nurse in Charge (or Team Leader) meets with the patient to gather information, and completes as many fields as possible on the Patient Grievance Status Report within 72 hours of being notified and informs the CM.</u></p> <p><u>The CM reviews the Patient Grievance Status Report daily. For any new grievances, CM meets with the patient within 5 business days to acknowledge, investigate and address the grievance. Note: MSW or other staff may also assist in assessing and resolving patient grievances, as appropriate.</u></p> <p><u>CM reports back to the patient when a resolution is attained or considered attained by the facility. Note: When the grievance cannot be immediately resolved, the CM must provide the patient/representative with updates periodically on progress.</u></p> <p>The CM ensures the following details are completed in the Quality Assessment and Performance Improvement (QAI) Patient Grievance Status Report:</p> <ul style="list-style-type: none"> ·Date grievance received. ·Mode of grievance (i.e. meeting, phone call, email, letter, fax) ·Intake Person 	

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	<p>stated he/she was "okay ... things appear the same." The log indicated Patient transferred to another dialysis facility and the complaint was marked as "resolved" on 1/24/24.</p> <p>During an interview with MSW 1 on 2/15/24 beginning at 3:47 PM, the social worker reported Patient #8 transferred to another dialysis facility because the patient was dissatisfied with the facility and had said it was "too loud" on the treatment floor. MSW 1 reported he/she received the above grievance from Patient on 12/13/23. The social worker reported in response to the complaint, the social worker provided Patient with the facility's grievance policy and chain of command and informed Clinic Manager 2 of Patient's concerns. MSW 1 reported when he/she followed up with Patient #8 regarding the grievance, Patient reported no improvement. The social worker reported the grievance was marked as "resolved" because Patient transferred to another facility and the corporate owner of the facility had a "Continuity of Care" division which would follow-up with Patient regarding his/her transfer.</p> <p>4. The review of an agency document titled "Admission/Discharge" report received on 2/16/24, evidenced patient #8 was transferred to another facility on 02/05/24.</p> <p>The review of Patient #8's clinical record evidenced a discharge summary dated 02/05/24; the record failed to evidence why Patient #8 was discharged from the facility.</p> <p>During a phone interview on 02/16/24 at 10:42 AM, Patient #8 indicated there was always loud music and yelling on the in-center hemodialysis treatment floor. The staff were very blasé and acted like it was not a medical facility. Patient #8</p>		<ul style="list-style-type: none"> ·Patient Initials ·Nature of the grievance ·Findings of the investigation ·Grievance referred to (if any) ·Resolution and any corrective actions taken. ·Any follow-up related to the grievance Note: Even if a patient's grievance is resolved quickly, the CM must document the complaint and the actions taken to resolve it. ·The CM ensures that all patient grievances are reported to the QAI Committee ·When a grievance cannot be resolved at the facility level: <ul style="list-style-type: none"> ·CM brings the grievance to the attention of the Director of Operations (DO) or Area Manager (AM) ·The DO/AM contacts the patient within 5 business days to acknowledge, investigate and address the grievance. ·The DO/AM attempts to resolve the grievance as soon as possible. Note: If the grievance cannot be immediately resolved, the DO/AM provides the patient/representative with updates periodically on progress. ·The DO/AM ensures that all patient grievances are reported to the QAI Committee and to the Governing Body. ·The facility QAI Committee must ensure that: 	

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE GARY			STREET ADDRESS, CITY, STATE, ZIP CODE 3290 GRANT ST GARY, IN 46408		
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	<p>indicated the staff didn't care about Patients, it was ghetto. Staff would hang their lab coats around their neck and then they would brush against you with the sleeves of their street clothes. Patient #8 indicated how were they to know if the staff had a dog licking all over their sleeve or where the sleeve had previously touched. Patient #8 indicated the nurses were as bad as the PCTs. Patient #8 indicated staff would go person to person with the same gloves, put a glove on one finger to use the machine, or hold their access site. Patient #8 indicated they could not take it, indicated when they would complain about the music and the unsanitary practices, staff indicated Patient #8 complained too much. Patient #8 stated "My rights were violated there," indicated if they said something to staff about what they didn't like, the staff would get snotty. Patient #8 indicated he/she had the right to say how they felt, but staff did not listen. Patient #8 indicated when he/she said something about loud music, they would say what you don't like music. Patient #8 indicated Staff would play on their phone more than a 17-year-old and not pay attention to Patients. Patient #8 indicated on one visit, they had to yell over the music to notify staff, that their access site had started to bleed, as no one was paying attention. Patient #8 indicated they were told all they did was complain. Patient #8 stated, "I didn't feel I should have to go through that," Patient #8 indicated they showed up for their last dialysis treatment and staff told Patient #8 they were not to be there. Patient #8 indicated he/she were scheduled, the PCT left and returned and then said, "Fine, they said you can be here."</p> <p>During an interview on 02/16/2024 at 2:40 PM, Clinic Manager 2 indicated from his/her understanding Patient #8 transferred to another</p>		<ul style="list-style-type: none"> ·Patient Grievance Status Report is completed and presented each month. ·Data trends are reviewed to improve patient care. ·If needed changes are identified, actions taken are documented within the QAI minutes. ·Minutes of the Governing Body meeting must include: <ul style="list-style-type: none"> ·Detailed description of the patient's grievance ·Pertinent information regarding the grievance ·Response to the patient ·Description of the outcome <p>On 2/20/24 & 2/21/24, all facility patients were re-educated on Patient's Rights and Responsibilities as well as the Patient Grievance process inclusive of the FKC Patient handout titled "What to Do if You Have a Concern" and "Important Numbers". A signed acknowledgement of receipt of the Patient Grievance Procedure was placed in the patients' medical record. All patients also received a copy of the Patient Rights and Responsibilities List and a signed copy of the Acknowledgement of Receipt of FMCNA Patient Rights and Responsibilities was placed in their medical record.</p> <p>The Clinical Manager will verify compliance with the above policies</p>		

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	unit because there were Patients around Patient #8 who would play music during treatment, and Patient #8 was upset because it was too loud. The Clinic Manager indicated staff would sometimes play music during the holidays and on Friday afternoons, but it was at an acceptable level, or the Clinic Manager would have staff turn it down. Clinic Manager 2 indicated Patient #8 did not express this to him/her, but it was the Clinic Manager's understanding of why Patient #8 left.		<p>by performing a daily review of the grievance log for 2 weeks then weekly times 4 weeks, beginning 2/21/24. Additionally, the Clinic Manager will be responsible for ensuring the patient grievance process is followed.</p> <p>Effective 3/21/24, Clinical Manager will conduct a daily review of the grievance log and ensuring the patient grievance process is followed, inclusive of, but not limited to, the investigation and documented resolution for 2 weeks then weekly times 4 weeks utilizing Grievance Log Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance.</p> <p>Additionally, two members of the Interdisciplinary Team (IDT), will meet with any patient within 72 hours of being notified of the grievance to assess the nature of the grievance and continue through investigation and follow-up. Documentation of findings will be discussed in QAI and noted in the meeting minutes.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of</p>	

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V 0467 Bldg. 00	494.70(a)(16), (17) PR-INFORMED-MAY FILE INT/EXT GRIEVANCE ANON		<p>Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p>		

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	<p>The patient has the right to-</p> <p>(16) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and</p> <p>(17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.</p> <p>Based on record review and interview, the dialysis facility failed to ensure all patients remained free from retaliation for filing complaints with the State Agency (SA) and/or with the facility for 1 of 1 active patient which the staff indicated they reported a complaint to the SA and/or facility (Patient #3).</p> <p>Findings include:</p> <p>1. The review of facility policy titled "Patient Grievance," dated 1/02/14, indicated all patients had the right to file a grievance at any time and could be filed written or verbally. The policy also indicated any grievance "that involves a situation or practice that may place patients or staff members in immediate danger must be resolved immediately."</p> <p>2. During an interview with Patient #3 on 2/14/24 beginning at 9:09 AM, Patient reported that on 02/09/24, Patient Care Technician (PCT) 1 scratched and slapped him/her while setting up Patient's dialysis treatment. Patient reported he/she had previously filed a complaint with the facility against PCT 1, so the technician was only supposed to "push the buttons" on the patient's dialysis machine and not provide direct patient care, however on 2/09/24, the facility was short-staffed and PCT 1 had to set up the patient's</p>	V 0467	<p>On 2/20/24, the Clinical Manager and Manager of Social Work held a staff meeting to provide education and to reinforce the expectations and responsibilities of the facility staff on the policies below.</p> <p>On 3/18/24 & 3/19/24, after receipt of the Statement of Deficiencies, the Social Work Managers met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> -Patient Grievance version 3 -Patient Grievance Procedure version 3 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -Any patient treated at an FMCNA dialysis facility has the right to file a grievance at any time. -Any grievance that involves a situation or practice that may place patients or staff members in immediate danger must be resolved immediately. -All patient grievances received 	03/22/2024

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	<p>dialysis treatment. Administrator came to Patient's chairside shortly after to discuss the alleged incident. Patient #3 reported during his/her conversation with Administrator, the employee told Patient he/she was aware Patient had filed complaints before with the SA. Patient #3 reported Administrator denied the alleged incident between the Patient #3 and PCT 1 occurred.</p> <p>The review of the facility's adverse event log evidenced an event documented on 3/22/23 by PCT 1. The event report indicated Patient #3 "became loud and argumentative" with the technician and refused to allow the technician to continue working with Patient.</p> <p>During an interview with PCT 1 on 2/14/24 beginning at 12:00 PM, the technician reported he/she had "issues" with Patient #3 prior to the 2/09/24 alleged incident. PCT 1 reported in 2023, Patient became upset when the technician would not put the patient's shoes on. PCT 1 reported Patient #3 filed a complaint regarding the 2023 incident and since then, the technician would limit his/her work with Patient #3 to only managing the patient's dialysis machine.</p> <p>Patient #3's medical record included a Progress Note documented on 3/22/23 by MSW 1. The note indicated PCT 1 reported during treatment, Patient #3 "became verbally abusive because [Patient] disagreed" about his/her dialysis prescription orders. Patient reported he/she did not want PCT 1 to continue to work with him/her.</p> <p>The review of an audio recording of Patient #3 and Administrator's interaction on 02/09/24 evidenced during the interaction, Administrator stated he/she was aware Patient had made complaints to the SA. When Patient denied</p>		<p>at the facility must be reported to the QAI Committee and to the Governing Body:</p> <ul style="list-style-type: none"> The intent of QAI review is to use patient grievances and trends to identify opportunities to improve care. Written documentation of the grievances and the actions taken to resolve it must be available in the QAI minutes. <p>On 2/20/24 & 2/21/24, all facility patients were re-educated on Patient's Rights and Responsibilities as well as the Patient Grievance process inclusive of the FKC Patient handout titled "What to Do if You Have a Concern" and "Important Numbers". A signed acknowledgement of receipt of the Patient Grievance Procedure was placed in the patients' medical record. All patients also received a copy of the Patient Rights and Responsibilities List and a signed copy of the Acknowledgement of Receipt of FMCNA Patient Rights and Responsibilities was placed in their medical record.</p> <p>The Clinic Manager will be responsible for observing staff/patient interactions by performing a daily observation of the treatment floor before, during and after patient treatments for 2 weeks and then weekly times 4 weeks, beginning 2/21/24. Any</p>	

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	<p>he/she had filed complaints with the SA, Administrator stated "yes you have ... I know everything." Administrator stated the alleged assault by PCT 1 did not occur, as if it had, the technician would be "in a police car."</p> <p>During an interview with Registered Nurse (RN) 1 on 02/14/24 beginning at 11:24 AM, the employee reported there was "always drama" with Patient #3 and the patient was "always complaining about this and that." RN 1 stated "everybody knows" Patient #3 had called the SA and complained about the facility in the past. RN 1 documented Patient #3 had "called out" the employee to other staff before.</p> <p>The review of facility's adverse event log evidenced an event documented on 5/31/23 by RN 1. The event report indicated Patient #3 was "loud and argumentative and yelling with techs." Patient reportedly "continued ranting in waiting room" about RN 1.</p> <p>The review of facility's grievance log indicated on 8/09/23, Patient #3 filed a verbal grievance with Medical Social Worker (MSW) 1. The log indicated Patient wanted to file a grievance against RN 1 because the nurse administered fluid when Patient's blood pressure dropped and the Patient thought he/she was becoming "ill" because of the additional fluid.</p> <p>During an interview with Employee C on 02/14/24 beginning at 12:40 PM, the employee reported the last time the SA conducted a survey of the facility was due to Patient #3 filing a complaint.</p> <p>3. The review of the facility's grievance log for 2/14/23 - 2/14/24 indicated on 12/13/23, Patient #8 filed a verbal grievance with MSW 1. The log</p>		<p>inappropriate behaviors identified, including, but not limited to, retaliation for filing complaints with the State Agency and/or with the facility will be immediately addressed, the appropriate course of action implemented, and with documentation noted in the employee personnel file.</p> <p>The Clinic Manager will be responsible for observing staff/patient interactions by performing a daily observation of the treatment floor before, during and after patient treatments for 2 weeks and then weekly times 4 weeks, beginning 3/21/24. Any inappropriate behaviors identified, including, but not limited to, retaliation for filing complaints with the State Agency and/or with the facility, will be immediately addressed, the appropriate course of action implemented, and with documentation noted in the employee personnel file. Additionally, two members of the Interdisciplinary Team (IDT), will meet with any patient within 72 hours of being notified of the grievance to assess the nature of the grievance and continue through investigation and follow-up. Documentation of findings will be discussed in QAI and noted in the meeting minutes.</p> <p>The Medical Director will review the results of audits each month</p>	

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	indicated Patient was "very agitated," reported he/she "can't get any rest due to the noise in the clinic ... the PCT's 'talk to much' [sic] ... music was playing and [Patient #8] did not understand why [he/she] has to listen to music" The log indicated Patient's family member had suggested noise-cancelling headphones, but Patient could not afford them. The log indicated MSW 1 spoke with Patient #8 to follow-up regarding the grievance and Patient stated he/she was "okay ... things appear the same." The log indicated Patient transferred to another dialysis facility.		<p>at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p>		

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V 0469 Bldg. 00	<p>494.70(b)(2) PR-RECEIVE WRITTEN NOTICE 30 DAYS PRE IVD The patient has the right to-</p> <p>(2) Receive written notice 30 days in advance of an involuntary discharge, after the facility follows the involuntary discharge procedures described in §494.180(f)(4). In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed.</p> <p>Based on record review and interview, the dialysis facility failed to ensure all policies and procedures specific to involuntarily discharging a patient were followed for 1 of 1 patient in which the facility had initiated an involuntary discharge in February 2024 (Patient #3).</p> <p>Findings include:</p> <p>1. The policy titled "Routine and Involuntary Patient Discharge," dated 9/04/19, indicated the Medical Director was to ensure no patient was involuntarily discharged unless "the facility can no longer meet the patient's documented medical needs ... the patient's behavior is deemed disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired." The policy indicated a patient at risk for involuntary discharge must be reassessed by the interdisciplinary team (IDT) and the IDT should document in the patient's medical record "the reassessments, ongoing problem(s), and effort(s) made to resolve the problem(s)." For involuntary</p>	V 0469	<p>Completion 3/22/24.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with members of the Interdisciplinary Team to reeducate and reinforce the expectations and responsibilities of the facility staff on policies as well as provide re-education on the electronic plan of care and appropriate documentation:</p> <ul style="list-style-type: none"> -Comprehensive Interdisciplinary Assessment and Plan of Care version 6 <p>On 2/20/24, the Clinical Manager and Manager of Social Work held a staff meeting to provide education and to reinforce the expectations and responsibilities of the facility staff on the policies below.</p> <p>On 3/18/24 & 3/19/24, after receipt</p>	04/05/2024

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	<p>discharges due to disruptive or abusive behavior, the facility should consult the "Disruptive Patient Behavior and Use of Behavioral Agreement" policy "at the first sign of disruptive or abusive behavior that does not rise to the level of a severe and immediate threat to the health and safety of others." The policy indicated prior to an involuntary discharge, "there must be evidence in the patient's medical record of the IDT's efforts to help the patient resolve any conflict or psychological issues contributing to the behavior." For involuntary discharges due to the facility's inability to meet the patient's needs, the facility should consider "all reasonable alternatives for continuing to provide care to the patient in the facility." The facility should conduct a meeting between the IDT and the patient and/or patient's representative "to discuss the patient's current status and barriers to providing a safe treatment environment for the patient" and discuss other treatment modalities and other locations that provide dialysis, such as a nursing home. The patient's medical record should include "documentation of all efforts to manage the patient's care and outcomes as well as all discussions with the patient and his/her representative."</p> <p>2. The policy titled "Disruptive Patient Behavior and Use of Behavioral Agreement," dated 4/04/12, indicated a patient at risk for involuntary discharge must be considered 'unstable' and reassessed by the interdisciplinary team (IDT). The patient's plan of care should be revised "to demonstrate interventions or resources agreed upon by the patient or determined necessary by the interdisciplinary team to resolve barriers or other issues contributing to the disruptive behavior." The policy indicated a behavioral agreement "should be considered" when "the</p>		<p>of the Statement of Deficiencies, the Social Work Managers met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> -Disruptive Patient Behavior and Use of Behavioral Agreement version 2 -Disruptive Patient Behavior and Use of Behavioral Agreement Procedure version 2 -Routine and Involuntary Discharge version 4 -Routine and Involuntary Discharge Procedure version 3 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -The frequency of the Comprehensive Interdisciplinary Assessment and Plan of Care are determined by the stability of the patient as determined by the physician, with input from the IDT. -Provide appropriate patient education to enable the patient to participate in the development of the Plan of Care. -Encourage both patient and family to participate in the Plan of Care discussions in whatever format the facility and attending physician develop. <p><u>-All incidents involving disruptive or dangerous behaviors must be immediately reported to the Team Leader or Clinical Manager. The Clinical Manager shall make an initial assessment of the situation.</u></p>	

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	<p>patient's behavior has escalated beyond the ability to be handled by an informal resolution process ... individual consultation with the patient's attending physician, clinical manager, [social worker] or a team meeting, patient/family meeting or patient education has not resulted in positive improvement in the patient's behavior ... the patient's behavior has potential to harm the patient or others ... the patient's behavior will potentially result in termination of dialysis services if not modified or stopped." The behavioral agreement was to "define what responsibilities or expectations the patient will need to meet to continue to receive services in the facility" and should indicate "consequences of continued disruptive behavior," including "possible discharge." The policy indicated once a behavioral agreement was implemented, the IDT would review the "progress of a patient's Behavioral Agreements on a monthly basis until the patient's behavior is either resolved, stabilized, or worsens to the extent that involuntary discharge is considered." The policy defined verbal abuse as "use of words, written or spoken, that demean, insult, belittle or degrade a person."</p> <p>3. During an interview with Patient #3 on 2/14/24 beginning at 9:09 AM, Patient reported that on 02/09/24, Patient Care Technician (PCT) 1 scratched and slapped him/her while setting up Patient's dialysis treatment. Patient reported he/she had previously filed a complaint with the facility against PCT 1, so the technician was only supposed to "push the buttons" on the patient's dialysis machine and not provide direct patient care, however on 2/09/24, the facility was short-staffed and PCT 1 had to set up the patient's dialysis treatment. Administrator came to Patient's chairside shortly after to discuss the alleged incident. Patient #3 reported during his/her</p>		<p><u>The Clinical Manager may include the facility Social Worker to assist with this assessment. The Clinical Manager informs the Medical Director and patients attending Nephrologist of the incident.</u></p> <p><u>Any patient at risk for transfer or discharge must be considered "unstable" and reassessed by the interdisciplinary team. The plan of care should be revised or adjusted, as indicated, to demonstrate interventions or resources agreed upon by the patient or determined necessary by the interdisciplinary team to resolve barriers or other issues contributing to the disruptive behavior.</u></p> <p><u>Document all the following in the medical record:</u></p> <p><u>The patient's disruptive behavior</u></p> <p><u>All interventions to defuse or address the patient's behavior.</u></p> <p><u>Outcome of these efforts.</u></p> <p><u>A Behavioral Agreement is a tool that should be considered for cases in which any of the following apply:</u></p> <p><u>The patient's behavior has escalated beyond the ability to be handled by an informal resolution process.</u></p> <p><u>Individual consultation with the patient's attending physician, Clinical Manager, MSW or a team meeting, patient/family meeting or patient education has not resulted in positive improvement in the patient's behavior.</u></p>	

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE GARY	STREET ADDRESS, CITY, STATE, ZIP COD 3290 GRANT ST GARY, IN 46408
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	<p>conversation with Administrator, the employee told Patient he/she was aware Patient had filed complaints before with the SA. Patient #3 reported Administrator denied the alleged incident between the Patient #3 and PCT 1 occurred and Patient asked how Administrator would like if their family member was being assaulted? Patient #3 reported Administrator became angry at Patient's comment regarding his/her family member. While leaving the treatment floor, Administrator yelled "take [him/her] off [the dialysis treatment]." Patient #3 reported on 2/12/24, he/she was notified by the facility he/she was being involuntarily discharged due to being "violent, aggressive" and "hitting, spitting."</p> <p>The review of an audio recording of Patient #3 and Administrator's interaction on 02/09/24 evidenced during the interaction, Administrator stated he/she was aware Patient had made complaints to the SA. When Patient denied he/she had filed complaints with the SA, Administrator stated "yes you have ... I know everything." Administrator stated the alleged assault by PCT 1 did not occur, as if it had, the technician would be "in a police car." Patient #3 stated PCT 1 wanted to "beat the garbage out of me ... we could have had a fight. I've had people assault me before." Administrator responded, "And you beat them up." Patient denied saying he/she had beat anyone up and patient hoped "somebody beat [the Administrator's family member] up like [PCT 1]'s doing." Administrator stated his/her family member was dead and Patient #3 responded stating "And maybe that's why." Administrator was heard yelling "So my [family member] is dead and [Patient #3] thinks [the family member]'s dead because [the family member] got beat up. You have lost your mind." Additional staff members could be heard coming to the</p>		<p>The patient's behavior has potential to harm the patient or others.</p> <p><u>The patient's behavior will potentially result in termination of dialysis services if it is not modified or stopped.</u></p> <p><u>The interdisciplinary team should review progress of a patient's Behavioral Agreements monthly until the patient's behavior is either resolved, stabilized, or worsens to the extent that involuntary discharge is considered.</u></p> <p>Except when a patient's behavior is a severe and immediate threat to the health and safety of others, a patient who is at risk for involuntary discharge must be reassessed by the interdisciplinary team (IDT). The IDT must document in the patient's medical record the reassessments, ongoing problems(s), and effort(s) made to resolve the problem(s).</p> <p><u>The medical director must be informed of and approve an immediate and 30-day involuntary discharge or transfer of a patient.</u></p> <p>Facility staff should consult the Disruptive Patient Behavior and Use of Behavioral Agreement policy at the first sign of disruptive or abusive behavior that does not rise to the level of a severe and immediate threat to the health and safety of others. Before involuntary transfer or discharge can occur,</p>	

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	<p>chairside and telling Administrator to walk away. Administrator could then be heard yelling in the distance "take [Patient #3] off [his/her dialysis treatment]."</p> <p>During an interview with Employee H on 02/14/24 beginning at 11:24 AM, the employee reported on 02/9/24, Patient #3 called the local police regarding the alleged assault by PCT 1. The employee reported a police officer and ambulance came to the facility and spoke with Patient at his/her chairside. Employee H reported the police officer also spoke with PCT 1, other employees including him/herself, and other patients, regarding the alleged incident.</p> <p>During an interview with Medical Director on 2/14/24 beginning at 1:25 PM, the physician reported he/she attempted to speak with Patient #3 on 02/12/24 regarding the incidents on 2/09/24 but Patient refused. Medical Director reported the facility had issues with Patient's behaviors in the past, but the physician was not aware of Patient being verbally or physically abusive towards staff. The physician had met with Patient #3 and Family Member A "on several occasions" to discuss Patient's behaviors within the past 6 months, however the meetings "didn't resolve anything." Medical Director reported he/she did not document the meetings. Medical Director was not aware of the facility enacting a behavioral agreement with Patient #3 prior to 02/12/24.</p> <p>During an interview with Medical Social Worker (MSW) 1 on 02/14/24 beginning at 3:20 PM, the social worker reported the facility had concerns with Patient #3's inappropriate behaviors in past. The social worker reported the facility IDT had tried to have meetings with Patient #3 regarding his/her behavior, but Patient would not come to</p>		<p>there must be evidence in the patient's medical record of the IDT's efforts to help the patient resolve any conflict or psychological issues contributing to the behavior.</p> <p>Consultation with the Regional Social Worker, Corporate Social Worker, and/or Clinical Services is advisable to prevent the likelihood of involuntary discharge. The Regional Social Worker will assess the situation to determine when additional assistance is needed from the Network or other parties.</p> <p>Effective 3/21/24, the Interdisciplinary Team will review progress of a patient's Behavioral Agreement monthly at their unstable plan of care meeting until the patient's behavior is either resolved, stabilized, or worsens to the extent that involuntary discharge is considered. Patients' stability status will be reviewed monthly and the plan of care at least annually, at a minimum, to review and update the plan of care. The Medical Director will review each month at the QAI Committee meeting.</p> <p>The Facility Administrator is responsible for reviewing, analyzing, and trending all data and monitoring results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p>	

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	<p>the meetings. The social worker reported he/she did not document attempts to conduct meetings as the clinic manager was responsible for setting up these meetings. MSW 1 reported the facility had not made a behavioral agreement with Patient #3 prior to 02/12/24 because the staff hoped Patient's behavior would improve.</p> <p>During an interview with Administrator on 02/14/24 beginning at 3:54 PM, Administrator reported the facility had tried previously to enact a behavioral contract with Patient #3, however Patient did not attend the IDT meeting. Administrator could not recall when this occurred. Administrator reported on 02/09/24, a local police officer came to the facility after being called by Patient #3. Per Administrator, the police officer informed the facility staff he/she would not file a report as the patient's allegations were unsubstantiated. Administrator reported he/she spoke with Patient #3 at his/her chairside regarding the alleged incident and Patient became "snappy," stated he/she should have hit PCT 1, and repeatedly brought up Administrator's deceased family member. Administrator reported Patient's "volume started increasing" and 2 employees came over to the chairside and advised Administrator to walk away. The employee reported as he/she was leaving the treatment floor, Administrator advised facility staff to end Patient #3's treatment early due to Patient saying he/she "should have" hit PCT 1. Later that day, Administrator met with MSW 1 and Corporate Employees 1 and 2 to discuss the incident. Administrator reported during the meeting, the facility and corporate staff determined Patient #3 was to be involuntarily discharged. Administrator reported during a meeting with Patient, Medical Director, MSW 1, Corporate Employee 2, and Administrator, Patient #3 was notified of the</p>		<p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 4/5/24.</p>	

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	<p>involuntary discharge and initiation of a behavioral agreement.</p> <p>The medical record evidenced the IDT last held a plan of care meeting for Patient #3 on 3/28/23. The plan of care failed to evidence the IDT noted any disruptive or abusive behaviors by Patient towards staff and/or other patients.</p> <p>During a follow-up interview with Administrator on 2/15/24 at 8:45 AM, Administrator reported Patient #3's plan of care was due to be updated in February 2024 and facility was waiting on all members of the interdisciplinary team (IDT) to update his/her portions of the comprehensive assessment before it could hold a Plan of Care meeting.</p> <p>The record included a "Patient Discharge Letter," dated 02/12/24, which indicated Patient was to be involuntarily discharged, effective 3/12/24, for "behavior that is disruptive and abusive to the extent that it impairs the delivery of care to you or the ability of the facility to operate effectively; the facility can no longer meet your documented needs." The letter indicated on 02/09/24, Patient #3 called the local police department "because [he/she] stated a PCT tried to assault [him/her]. When the staff attempted to talk to [patient, he/she] became verbally aggressive, loud, and disruptive and stated [he/she] should have hit the PCT."</p> <p>The record included a "Behavioral Agreement" for Patient #3, signed by Clinic Manager 2 and Medical Director on 02/12/24. The behavioral agreement indicated Patient needed to "be considerate of other patients and staff," including not using "swear words, threats, or other foul language to degrade, hurt, or be disrespectful to</p>			

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	<p>staff or other patients" and "not acting in a way that makes other people in the clinic uncomfortable or afraid for their safety, such as kicking, hitting, threatening, cursing, and yelling." The behavioral agreement was to be "reviewed by the Clinic Manager on a monthly basis" with Patient. The behavioral agreement failed to evidence the patient's impending involuntary discharge.</p> <p>The record indicated prior to Patient #3's involuntary discharge notification on 02/12/24, the last documented nursing comprehensive assessment was completed on 4/05/23.</p> <p>The record included a Clinical Note documented on 11/16/22 at 10:30 by MSW 1. The note indicated the social worker spoke with Patient #3 and Family Member A regarding "issues" Patient #3 was having at the facility. MSW 1 noted Patient #3 and Family Member A had multiple complaints about the facility, including "problems with a PCT" and "numerous complaints against the staff." The note indicated MSW 1 informed the clinic manager of Patient's complaints. The social worker noted the clinic manager had stated several patients had complained about Patient #3 and the patient's "behaviors. [Patient #3] was observed throwing a blood pressure cuff and yelling and hitting dialysis chair."</p> <p>The record included a Progress Note documented on 11/19/22 by MSW 1. The note indicated ESRD Physician 1, Former Clinic Manager B, and MSW 1 met with Patient #3 and Family Member A. The note indicated Patient had several complaints regarding his/her care and facility staff. ESRD Physician 1 summarized Patient's treatment and "problems with low blood pressure." The physician suggested Patient #3 consider an</p>			

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	<p>alternative treatment modality. MSW 1 documented Former Clinic Manager B was to "talk to staff for their version of incident." The record failed to evidence details regarding the "incident" to which the note referred.</p> <p>The record included a Progress Note documented on 11/30/22 by MSW 1. The note indicated Administrator and MSW 1 met with Patient #3 to discuss "current incident." Patient #3 reported he/she felt like the facility staff did not like him/her and Patient had "issues regarding [his/her] care." MSW 1 documented the facility provided Patient #3 with educational materials on alternative treatment modalities, Patient's rights and responsibilities, and "Thriving without Fear/Managing Retaliation." The record failed to evidence details regarding the "incident" mentioned, any follow-up by facility staff regarding the 11/19/22 or 11/30/22 meetings with Patient, nor Patient's responses to the 11/19/22 and/or 11/30/22 meetings.</p> <p>The record included a Clinical Note documented on 2/13/23 by Administrator. The note indicated Administrator spoke with Patient #3 and Family Member A regarding Patient and family member's multiple concerns. Family Member A reported he/she had overheard a technician telling Patient #3 to "just get in the damn chair." Administrator asked Patient if he/she wanted to transfer to another dialysis unit and Patient declined. The note indicated Patient #3 and Family Member A "began to get very agitated and rude" to Administrator during the conversation. Administrator documented he/she advised Patient #3 to "practice patience, be kind, and respectful to all staff at all times, as the PCT today that took care of Patient was crying and upset by the way [he/she] was treated by Patient." Patient reported</p>			

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	<p>he/she was not rude nor yelled at the employee. Administrator documented after the discussion with Patient #3 and Family Member A, the technician reported he/she feared providing care to Patient #3 due to Patient being "rude and condescending and [the technician was] scared to make a mistake as [he/she] might be reported to leadership." The record failed to evidence any follow-up nor documenttion of Patient's response to the meeting, including if there was any improvement to Patient's reported behaviors.</p> <p>The review of the facility's adverse event log evidenced an event documented on 3/22/23 by PCT 1. The event report indicated Patient #3 "became loud and argumentative" with the technician and refused to allow the technician to continue working with Patient.</p> <p>During an interview with PCT 1 on 2/14/24 beginning at 12:00 PM, the technician reported he/she had "issues" with Patient #3 prior to the 2/09/24 alleged incident. PCT 1 reported in 2023, Patient became upset when the technician would not put the patient's shoes on. PCT 1 reported Patient #3 filed a complaint regarding the 2023 incident and since then, the technician would limit his/her work with Patient #3 to only managing the patient's dialysis machine.</p> <p>Patient #3's medical record included a Progress Note documented on 3/22/23 by MSW 1. The note indicated PCT 1 reported during treatment, Patient #3 "became verbally abusive because [Patient] disagreed" about his/her dialysis prescription orders. Patient reported he/she did not want PCT 1 to continue to work with him/her. The social worker documented they would "continue to monitor/assist as needed." The record failed to evidence staff conducted any further follow-up</p>			

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	<p>regarding the incident.</p> <p>The facility's adverse event log evidenced an event documented on 5/31/23 by RN 1. The event report indicated Patient #3 was "loud and argumentative and yelling with techs." Patient reportedly "continued ranting in waiting room" about RN 1.</p> <p>The facility's adverse event log evidenced an event documented on 6/07/23 by PCT 2. The event report indicated Patient #3 pushed the technician away and would not allow the technician to perform care to Patient's central venous catheter (CVC). The report indicated Patient was "loud and argumentative."</p> <p>Patient #3's medical record included a Clinical Note documented on 6/13/23 by Administrator. The note indicated Administrator called both Patient #3 and Family Member A to attempt to schedule a meeting with the IDT, however Administrator was unable to reach either Patient or family member. The note failed to evidence the reason for the meeting. The record failed to evidence documentation of any further attempts to conduct a meeting between the IDT and Patient #3.</p> <p>The record included a Progress Note documented on 10/23/23 by MSW 1. The note indicated Clinic Manager 2 reported Patient #3 would "not listen to staff ... regarding [his/her] treatment. [Patient #3] will not adhere to treatment orders. [Patient #3] is calling staff murderers and killers and most staff are afraid to work with [him/her. The clinic manager] is trying to have a meeting" The record failed to evidence when the IDT held or attempted to hold a meeting with Patient #3 regarding his/her reported behaviors.</p>			

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	<p>The record included a Progress Note documented on 12/01/23 by MSW 1. The note indicated Clinic Manager 2 reported Patient #3 had "snatched an item" out of RN 3's hands and had been "disruptive." The note indicated the social worker would "continue to monitor/assist as needed." The record failed to evidence the IDT held or attempted to hold a meeting with Patient #3 regarding his/her reported behaviors.</p> <p>During an interview with MSW 1 on 2/15/24 beginning at 11:07 AM, the social worker reported the facility attempted to conduct a meeting with Patient #3 regarding his/her behavior after the October or December incidents but could not recall when the attempted meeting occurred. MSW 1 reported Clinic Manager 2 was responsible for setting up the meeting, so the social worker did not document these attempts. MSW 1 reported Patient did not attend the meeting. The social worker could not recall any further interventions were performed by the facility regarding Patient's behavior.</p> <p>The record included a Progress Note documented on 2/12/24 by MSW 1. The note indicated a meeting was held with "managers" regarding possible involuntary discharge of Patient #3. MSW 1 documented "per meeting with management, [Corporate Employee 1], clinic will start involuntary discharge."</p> <p>The record included a second Progress Note documented on 2/12/24 by MSW 1. The note indicated the IDT met with Patient #3. During the meeting, Patient #3 was given a notification of involuntary discharge "due to disruptive behaviors and threats to staff" and Patient was given a behavioral agreement.</p>			

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	<p>The review of the facility's adverse event log between 2/14/23 - 2/14/24 evidenced 2 adverse events involving Patient #3 dated 02/09/24. The log included:</p> <p>a. An adverse event for "hemolysis" documented by PCT 1 at 9:19 AM. The event report indicated after performing Patient #3's CVC care, the technician secured Patient #3's CVC lines to Patient's left shoulder. Patient began to pull the lines and "direct where [he/she] would like to place the tape." PCT 1 documented he/she asked Patient to loosen the arterial line "to prevent the machine from alarming due to noticing restriction." Patient #3 "became argumentative," telling the technician "that is not the reason for the machine alarming," and asking the technician to "just do what [he/she] was asked to do." PCT 1 documented he/she placed tape where Patient requested and Patient "yelled out ... I know you just didn't hit me! Back away from me!" The event report indicated the technician [sic] "confessed that [he/she] did not hit [Patient #3]," left Patient's station, and informed the facility's management. PCT 1 documented Patient #3 "called the police to make a report."</p> <p>Review of Patient #3's clinical record evidenced Patient's dialysis treatment began on 2/09/24 at 7:04 AM. Review of the police report filed regarding the police investigation of PCT 1's alleged assault against Patient indicated the assault was initially reported to the police at 7:09 AM. The police officer's last radio log was at 8:16 AM to report the investigation was complete. Patient #3's treatment floor sheet indicated the patient's treatment ended at 8:57 AM, which was after Patient and Administrator spoke.</p>			

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V 0504 Bldg. 00	<p>b. An adverse event for "Dialysis Weight/[Ultrafiltration] Goal Variance" documented by Administrator at 3:11 PM. The event report indicated Patient #3 "had a behavioral occurrence while at treatment ... [Patient] had an outburst, called the police alleging that [he/she] was assaulted by a PCT. [Patient #3] threatened stating that [he/she] 'should've fight [sic] [the technician] back.' [Patient #3's] treatment was immediately ended." The event report indicated Patient #3 was discharged.</p> <p>4. The review of the facility's list of unstable patients for November 2023 - February 2024, provided by the Administrator on 2/15/24, failed to evidence Patient #3 was listed as "unstable" for any of these months.</p> <p>494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs.</p> <p>Based on observation, record review, and interview the dialysis facility failed to ensure patient pre/post and intradialytic blood pressure were being assessed and managed in 2 of 2 in-center hemodialysis records reviewed with abnormal blood pressures (Patients #4 and #16).</p> <p>Findings include:</p> <p>1. An agency policy titled "Charge Nurse Notification Protocol," indicated the nurse should be notified of pretreatment systolic blood</p>	V 0504	<p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on policies listed below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the</p>	03/22/2024

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	<p>pressures (SBP) of >200 or < 90 and Diastolic BP > 100 or <50. During treatment, the nurse should be notified of SBP > 160 or < 90. Pulse >100 or < 60. Post treatment the nurse should be notified of SBP > 160 or < 90. Pulse >100 or < 50, SBP drops of 25 points or more, and DBP drops of 15 points or more.</p> <p>2. An agency policy revised 9/1/2023, titled "Patient Assessment Pre & Post Dialysis indicated the nurse responsible will be notified if the vital signs are not within normal limits.</p> <p>3. Clinical record review for Patient #4, start of care 12/30/2011, included a review of the dialysis treatment sheets from 1/31/2024 through 2/9/2024 and evidenced the following:</p> <p>On 2/9/2024, the documentation evidenced Patient #4's pretreatment BP was 192/136 sitting and 212/249 standing; at 6:37 AM was 151/109 and pulse was 114; at 8:30 AM, BP was 182/107, and pulse was 150; at 9:00 AM, BP was 173/103 and pulse was 128; at 9:32 BP was 161/116; at 10:03 AM, BP was 166/115 and post-treatment BP was 175/104 sitting and 181/107 standing. The record failed to evidence the clinical staff implemented the policy and procedures for the treatment of blood pressure.</p> <p>4. Clinical record review for Patient #16, start of care 9/22/2014, included a review of the dialysis treatment sheets from 2/2/2024 through 2/14/2024 and evidenced the following:</p> <p>On 2/6/2024, the documentation evidenced Patient #16's BP at 10:54 AM was 197/91; at 11:02 AM, BP was 195/97. The record failed to evidence the clinical staff implemented the policy and procedures for the treatment of blood pressure.</p>		<p>expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> -Patient Assessment and Monitoring version 4 -Nursing Supervision and Delegation version 6 <p>Emphasis was placed on: Direct patient care staff may collect data such as weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. If the PCT/LPN note any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the registered nurse must assess the patient.</p> <p><u>Report to the nurse:</u> <u>Systolic blood pressures greater than 180 mm/Hg</u> <u>Diastolic blood pressure greater than 100 mm/Hg</u> <u>Blood Pressure less than or equal to 100 mm/hg systolic</u></p> <p>Any complaints by the patient before, during, or after treatment.</p> <ul style="list-style-type: none"> -The RN is accountable for delivering care within the framework of the nursing process. The RN uses clinical findings to formulate nursing diagnoses and prioritize problems according to patient need. -The Registered Nurse will assess/reassess any findings 		

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	<p>On 2/15/2024, the documentation evidenced Patient #16's BP at 10:39 AM was 139/108; at 11:30 AM, BP was 196/100; at 12:08 PM, BP was 195/89; and at 2:08 PM, BP was 187/100. The record failed to evidence the clinical staff implemented the policy and procedures for the treatment of blood pressure.</p> <p>5. During an interview on 2/21/2024 at 9:45 AM, RN 5 indicated any abnormal blood pressure parameters for the patient should be reported to the Physician. She indicated the PCTs alert the RN for any blood pressure that is abnormal for the patient.</p>		<p>addressed pre or during treatment as needed.</p> <ul style="list-style-type: none"> The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction. <p>On 3/6/24, the Clinical Manager or designee will conduct audits on 10 treatment sheets daily, alternating shifts, with focus on ensuring patient pre/post and intradialytic blood pressures are assessed and managed utilizing Treatment Sheet Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Treatment sheet audits will continue daily until receipt of the Statement of Deficiencies is received and re-evaluated at that time.</p> <p>Effective 3/21/24, Clinical Manager or designee will conduct audits on 10 treatment sheets daily, alternating shifts, with focus on ensuring patient pre/post and intradialytic blood pressures are assessed and managed utilizing Treatment Sheet Audit Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once</p>	

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			<p>compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution</p>	

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V 0540 Bldg. 00	494.90 CFC-PATIENT PLAN OF CARE Based on record review and interview, the interdisciplinary team (IDT) failed to ensure the patient's plan of care was individualized, included measurable interventions, outcomes, or goals, evidenced interventions the patient and/or IDT was conducting to address disruptive behaviors, and the IDT met at least annually to review and update the plan of care (See V541); failed to ensure the physician was notified when an ICHD patient was below their Estimated Dry Weight (EDW) prior to treatment or when the ICHD patient's post-treatment weight was greater than/less than 1 kilogram of the ordered EDW, failed to ensure staff followed facility policies specific to the treatment of orthostatic hypotension, and failed to ensure patients were assessed and/or monitored per policy (See V543); failed to ensure the ICHD patient's dialysis prescription was followed during treatment specific to the blood flow rate (See V544); the clinic failed to ensure they provided the necessary care for patients to achieve appropriate albumin levels (See V545); the clinic failed to ensure they provided the necessary care for patients to achieve appropriate hemoglobin levels (See V547), and failed to ensure the plan of care was reviewed and signed by the patient, and if the patient	V 0540	of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 3/22/24. The Governing Body of this facility acknowledges its responsibility to ensure that the patient's plan of care is individualized, includes measurable interventions, outcomes and/or goal, evidenced interventions the patient and/or IDT conducts to address disruptive behaviors, and the IDT meets at least annually to review and update the plan of care, additionally, to ensure the physician is notified when an ICHD patient is below their estimate dry weight (EDW) prior to treatment or when the ICHD patient's post treatment was is greater than/less than 1 kilogram of the ordered EDW, policies specific to the treatment of orthostatic hypotension are followed, and patients are assessed and/or monitored per policy, as well as, to ensure the ICHD patient's dialysis prescription is followed during treatment specific to the blood flow rate. The Governing Body also acknowledges its	04/05/2024

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	<p>declined to sign, this would be indicated on the plan of care (See V556).</p> <p>The cumulative effects of these systemic issues resulted in the dialysis facility failing to implement and maintain the patient's plan of care. Fresenius Medical Care Gary was found out of compliance with 42 CFR 494.90 Patient plan of care.</p>		<p>responsibility to ensure that the necessary care for patients to achieve appropriate albumin and hemoglobin levels is provided and the plan of care is reviewed and signed by the patient, and if the patient declines to sign the plan of care, it is indicated on the plan of care.</p> <p>As such, the Governing Body held a conference call on 2/26/24 to review the information provided by the surveyors during this survey and actively participate in the development of the Plan of Correction. The Governing Body has committed to meet weekly to review the status of the Plan of Correction until all issues are resolved and the facility is back in compliance.</p> <p>The Governing Body met again on 3/18/24, to review the Statement of Deficiencies and develop the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution.</p> <p>The Governing Body began meeting weekly beginning 2/26/24 to review the results of the progress on the Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The Governing Body will determine when the frequency of these</p>	

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			<p>meetings may be reduced to the regular quarterly schedule. Effective immediately:</p> <ul style="list-style-type: none"> -The Clinical Manager will analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee. -A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda. -The QAI Committee is responsible for reviewing and evaluating the Plan of Correction to ensure it is effective and providing resolution of the issues. -The Facility Administrator will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. -The Governing Body, at its meeting of 2/26/24, designated the Facility Administrator to serve as Plan of Correction Monitor and provide additional oversight. They will participate in QAPI and Governing Body meetings. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement 	

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V 0541 Bldg. 00	494.90 POC-GOALS=COMMUNITY-BASED STANDARDS 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		of Deficiency through to resolution as well as ensure the Governance of the Facility is presented current and complete data to enhance their governance oversight role. Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction, and oversight and the QAI Committees ongoing monitoring of facility activities. These are available for review at the facility. The responses provided for V 541, V 543, V 544, V 545, V 547, and V 556 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies cited within this Condition are corrected to ensure ongoing compliance.	

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	<p>current evidence-based professionally-accepted clinical practice standards.</p> <p>Based on record review and interview, the interdisciplinary team (IDT) failed to ensure the patient's plan of care was individualized, included measurable interventions, outcomes, or goals, evidenced interventions the patient and/or IDT was conducting to address disruptive behaviors, and the IDT met at least annually to review and update the plan of care, for 8 of 9 active in-center hemodialysis records reviewed (Patient #3, 4, 7, 10, 11, 14, 16, and 17).</p> <p>Findings include:</p> <p>1. A review of facility policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care," dated 7/3/2023, indicated the stable patient's plan of care should be updated annually. The IDT was expected to "interact and share information from the comprehensive assessment to facilitate the development of the plan of care." The policy indicated the plan of care must include "measurable and expected outcomes and an estimated timetable to achieve these outcomes."</p> <p>2. A review of facility policy titled "Disruptive Patient Behavior and Use of Behavioral Agreement," dated 4/04/12, indicated a patient at risk for involuntary discharge must be considered 'unstable' and reassessed by the interdisciplinary team (IDT). The patient's plan of care should be revised "to demonstrate interventions or resources agreed upon by the patient or determined necessary by the interdisciplinary team to resolve barriers or other issues contributing to the disruptive behavior."</p>	V 0541	<p>On 3/18/24, after receipt of the Statement of Deficiencies, the Clinical Technology Education Manager held a virtual meeting with the IDT to review, reeducate and reinforce the expectations and responsibilities of the IDT on policies:</p> <ul style="list-style-type: none"> ·Comprehensive Interdisciplinary Assessment and Plan of Care version 6 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> ·<u>The patient's Plan of Care will be guided and developed based on the findings identified in the Comprehensive Interdisciplinary Assessment.</u> ·The comprehensive interdisciplinary assessment includes the following: <ul style="list-style-type: none"> ·Current health status including co-morbid conditions. ·Evaluation of appropriateness of dialysis prescription (including at least a monthly Kt/V or equivalent measure on HD patients or at least every 4 months on PD patients by calculating a delivered wKt/V or equivalent measure) <ul style="list-style-type: none"> ·Blood pressure and fluid management needs ·Prescribed lab testing, immunization history and medication history 	04/05/2024

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	<p>3. A review of Patient #3's medical record included a Progress Note documented on 2/12/24 by MSW 1. The note indicated the IDT met with Patient #3 and notified Patient of his/her involuntary discharge from the facility "due to disruptive behaviors and threats to staff."</p> <p>The record evidenced Patient's current plan of care, dated 3/28/23. The plan of care failed to evidence the IDT noted any disruptive or abusive behaviors by Patient towards staff and/or other patients.</p> <p>During an interview with Administrator on 2/15/24 at 8:45 AM, Administrator reported Patient #3's plan of care was due to be updated in February 2024 and facility was waiting on all members of the IDT to update his/her portions of the comprehensive assessment before it could hold a Plan of Care meeting.</p> <p>A review of the facility's list of unstable patients for November 2023 - February 2024, provided by the Administrator on 2/15/24, failed to evidence Patient #3 was listed as "unstable" for any of these months.</p> <p>4. A review of Patient #7's medical record evidenced the IDG last completed a plan of care meeting to review the patient's plan of care on 12/19/22.</p> <p>During an interview with Administrator on 2/22/24 beginning at 11:35 AM, Administrator reported all members of the IDT completed their portions of Patient's comprehensive assessment and updated the plan of care according to the assessments, in November 2023. Administrator reported the IDG did not hold a meeting to review the plan of care</p>		<ul style="list-style-type: none"> ·Evaluations of factors associated with anemia and potential treatment plan for anemia, including administration of erythropoiesis-stimulating agents. ·Evaluation of factors associated with renal bone disease. ·Evaluation of nutritional status by a qualified dietitian ·Evaluation of psychosocial needs by a qualified social worker ·Evaluation of dialysis access types and maintenance ·Evaluation of the patient abilities, interest, preferences, and goals, including the desired level of participation in the dialysis care process, the preferred modality and setting and the patient expectations for care outcomes ·Evaluation of suitability for a transplant referral ·Evaluation of family and other support systems ·Evaluation of current patient physical activity level ·Evaluation of referral to vocational and physical rehabilitation services ·<u>The patient plan of care will be developed from the findings gathered in the CIA. The IDT members are expected to interact and share information from the comprehensive assessment to facilitate the development of the plan of care.</u> ·<u>Problems electronically generated from the CIA must be</u> 	

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	<p>due to staffing issues and the facility discovered Patient #7 did not have an updated POC in "early February." Administrator reported the IDG was in the process of updating Patient's comprehensive assessment and Patient was scheduled for his/her annual POC review in February 2024.</p> <p>5. A review of Patient #11's medical record included a plan of care dated 3/23/23. The plan of care evidenced an area of focus for Diabetes Management which indicated the goal was for Patient's A1C (blood test which shows the patient's average blood sugar levels over a 3 month period) results to be within the "normal range or as specified by the Physician." The plan of care's intervention for this focus area included "to add, adjust, or discontinue diabetes medications" and failed to be individualized for Patient.</p> <p>The plan of care evidenced an area of focus for Blood Pressure and fluid management, with a goal to achieve BP control "as specified by the patient's physician." The plan of care failed to evidence what was the "physician-specified" blood pressure goal. The plan of care's intervention for this focus area included to "add, adjust, and to discontinue BP medications" and failed to evidence individualized Patient goals.</p> <p>6. A review for Patient #10's medical record included a plan of care dated 07/31/2023. The plan of care included a goal for Patient to "verbalize decreased pain levels." Registered Nurse (RN) 4 completed the nursing portion of Patient's comprehensive assessment on 7/07/23 which indicated Patient denied pain and indicated no follow up plan was required.</p> <p>A review of Patient #10's treatment sheets dated 02/02/2024, 02/07/2024, 02/09/2024, 02/12/2024, and</p>		<p><u>reviewed by the IDT and determine whether the problem will be included in the patient's POC. Problems electronically generated from the CIA and not included in the POC, must have a reason documented as to why the problem wasn't included such as determining that the condition is chronic.</u></p> <p><u>·The Plan of Care must include measurable and expected outcomes and an estimated timetable to achieve these outcomes.</u></p> <p><u>·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 timeframe:</u></p> <p><u>·The Interdisciplinary team must adjust the patient's Plan of Care and document changes made to the POC.</u></p> <p><u>·Implement the Plan of Care changes to address the identified issues.</u></p> <p>Effective 3/21/24, Clinical Manager will conduct a review of all care plans due within the month to ensure goals set are individualized, includes measurable goals, outcomes, and goals evidence interventions, patient disruptive are addressed and the IDT meets at least annually at a minimum to review and update the plan of care.</p>	

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	<p>02/14/2024 failed to evidence Patient with complaints / reports of pain.</p> <p>7. A review for Patient #4's medical record included a plan of care dated 7/31/2023. The plan of care evidenced Patient had an area of focus for Diabetes Management documented 8/8/2022, which indicated the Patient's A1C (blood test which measures blood sugar levels over 3-month period) results would be in the "normal range or as specified by the Physician." The plan of care's intervention for this focus area included "to add, adjust, or discontinue diabetes medications" and failed to evidence the plan was individualized for Patient.</p> <p>8. A review for Patient #14's medical record included a plan of care dated 01/29/2024. The plan of care evidenced an area of focus for Diabetes Management which indicated the Patient's A1C results would be in the "normal range or as specified by the Physician." The plan of care's intervention for this focus area included "to add, adjust, or discontinue diabetes medications" and failed to evidence the plan was individualized for Patient.</p> <p>The plan of care evidenced an area of focus for Blood Pressure and fluid management, with a goal to achieve BP control "as specified by Patient's physician." The plan of care failed to evidence what was the "physician-specified" blood pressure goal. The plan of care's intervention for this focus area included to "add, adjust, and to discontinue BP medications" and failed to evidence the plan was individualized for Patient.</p> <p>9. A review for Patient #16's medical record included a plan of care dated 4/28/2023 which evidenced Patient had areas of focus for "Dialysis Adequacy PD issues" and "Dialysis Access PD</p>		<p>Patients' stability status will be reviewed monthly and the plan of care at least annually, at a minimum, to review and update the plan of care. Monitoring for continued compliance will be done monthly through the ePOC Dashboard and any noncompliance will be noted in the monthly QAI meeting minutes.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p>	

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE GARY	STREET ADDRESS, CITY, STATE, ZIP COD 3290 GRANT ST GARY, IN 46408
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	<p>patient." The record indicated Patient #16 was no longer on PD dialysis and was receiving in-center hemodialysis.</p> <p>The plan of care evidenced an area of focus for Diabetes Management which indicated the Patient's A1C results would be in the "normal range or as specified by the Physician." The plan of care's intervention for this focus area included "to add, adjust, or discontinue diabetes medications" and failed to evidence the plan was individualized for Patient.</p> <p>The plan of care evidenced an area of focus for Blood Pressure and fluid management, with a goal to achieve BP control "as specified by the patient's physician." The plan of care failed to evidence what the "physician-specified" blood pressure was. The plan of care's intervention for this focus area included to "add, adjust, and to discontinue BP medications." This area of focus failed to be individualized for the patient.</p> <p>10. A review for Patient #17's medical record included a plan of care dated 9/25/2023. The plan of care evidenced the patient had an area of focus for Dialysis Adequacy Peritoneal dialysis (PD) issues. The record evidenced Patient #17 was no longer on PD dialysis and was receiving in-center hemodialysis.</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." The plan of care failed to evidence what the "physician-specified" blood pressure was. The plan of care's intervention for this focus area included to "add, adjust, and to discontinue BP medications." This area of focus failed to be individualized for the patient.</p>		<p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 4/5/24.</p>	

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V 0543 Bldg. 00	<p>11. During an interview on 2/22/2024 at 4:07 PM, the Clinic Manager reported the patient's plan of care was updated yearly unless a patient was unstable. Clinic Manager 2 reported the IDG did not update the plan of care for stable patients. The system used to create plans of care has interventions and goals the IDG could pick from for each patient, but these could not be edited. Clinic Manager 2 reported once a goal or intervention is added to the plan of care, if it is removed, it could not be subsequently re-added. The employee reported he/she did not know how the facility would be to make the plan of care individualized as patients' goals and interventions could change throughout the year.</p> <p>494.90(a)(1) POC-MANAGE VOLUME STATUS 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;</p> <p>Based on record review and interview, the dialysis facility failed to ensure the physician was notified when an in-center hemodialysis (ICHD) patient was below their Estimated Dry Weight (EDW) prior to treatment or when an ICHD patient's post-treatment weight was greater than/less than 1 kilogram of the ordered EDW for 4 of 9 active ICHD patient records reviewed (Patient #4, 14, 16, 17), failed to ensure staff followed facility policies specific to the treatment of orthostatic hypotension for 2 of 2 active ICHD patient records reviewed with orthostatic hypotension (Patient #9 and 10), and failed to ensure patients were assessed and/or monitored per policy in 6 of</p>	V 0543	<p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on policies listed below.</p> <p>Volume Management in ESRD Patients on Hemodialysis version 1 Patient Assessment and Monitoring version 4 Nursing Supervision and</p>	03/22/2024

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	<p>9 active ICHD patient records reviewed. (Patient #4, 9, 10, 14, 16, and 17).</p> <p>Findings include:</p> <p>1. The review of a facility policy titled "Volume Management in ESRD [End Stage Renal Disease] Patients on Hemodialysis," dated 9/7/2021, indicated "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 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. The facility policy titled "Patient Assessment and Monitoring," dated 5/1/2023, indicated "If the [Patient Care Technician (PCT) / Licensed Practical Nurse (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 [RN] Any abnormal finding confirmed by the RN 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</p>		<p>Delegation version 6</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <p style="padding-left: 40px;">Volume Management in ESRD Patients on Hemodialysis version 1</p> <p style="padding-left: 40px;">Patient Assessment and Monitoring version 4</p> <p style="padding-left: 40px;">Guidelines for Recognizing and Treating Orthostatic (Postural) Hypotension version 3</p> <p style="padding-left: 40px;">Nursing Supervision and Delegation version 6</p> <p>Emphasis was placed on: <u>·The registered nurse must evaluate each patient within an hour or according to state requirements to:</u></p> <ul style="list-style-type: none"> ·Confirm identity. ·Review the patient's condition. ·Review accuracy and completeness of treatment and patient data. ·Review patient treatment prescription and equipment parameters to verify correct settings, and if dialysis prescription is being followed. ·Confirm that the correct vascular access is being used, and that the access is visible. ·Observe patient's response 	

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	<p>minutes per state regulations ... The Registered Nurse will assess/reassess post-treatment as indicated."</p> <p>3. The review of a facility policy titled "Guidelines for Recognizing and Treating Orthostatic (Postural) Hypotension," dated 02/07/2022, indicated orthostatic hypotension was a drop in blood pressure [BP] from sitting to standing that was equal to or great than 20 mm Hg [millimeters of mercury, the measurement of blood pressure] systolic [top number of a blood pressure reading] or 10 mm Hg diastolic [bottom number of a blood pressure reading], the registered nurse would notify the nephrologist when orthostatic hypotension was not relieved by intervention, if the patient exhibits signs or symptoms of orthostatic hypotension the following steps should be followed: instruct the standing patient to sit back down in the dialysis chair and place the patient into modified Trendelenburg position, administer normal saline in bolus doses of 100-200 mL or otherwise prescribed by the patient's physician, evaluate patient's condition, take blood pressure and pulse after each normal saline administration, if after a total of 200mL of normal saline does not resolve the patient's signs and symptoms notify the registered nurse, reevaluate the patient's vital signs, if the patient continued to have blood pressure changes or symptoms of orthostatic hypotension the physician must be notified.</p> <p>4. The review of a facility policy titled "Nursing Supervision and Delegation," dated 5/1/23, indicated the following task may not be delegated: assessment of each patient preferably within one hour of treatment initiation in the clinic setting.</p> <p>5. The clinical record review for Patient #4, start of</p>		<p>to treatment.</p> <ul style="list-style-type: none"> ·Verify machine safety checks have been completed. ·Talk to the patient to elicit information such as changes in condition, response to treatment, new injuries, information/education needs or complaints, satisfaction with care. ·Fluid balance is an integral component of the HD treatment to prevent patient hyper- or hypovolemia both of which have been demonstrated to influence mortality and cardiovascular complications in ESRD patients on HD. <u>Registered nurse should complete a fluid assessment on all ESRD patients receiving HD treatments. Assessment should evaluate patients for hypo- and hypervolemia.</u> <ul style="list-style-type: none"> · <u>At a minimum, fluid assessment will include review of the following clinical indicators:</u> <ul style="list-style-type: none"> ·EDW ·Pre/Post Weight ·Post Weight comparison to EDW. ·Pre/Post Blood Pressure ·Orthostatic Hypotension: <u>A drop in blood pressure from sitting to standing that is equal to or greater than 20 mm Hg systolic or 10 mm Hg diastolic.</u> <ul style="list-style-type: none"> ·Lowest Intradialytic Blood Pressure ·Signs/symptoms of fluid overload ·Physical examination 	

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	<p>care 12/30/2011, included a review of the dialysis treatment sheets from 1/31/2024 through 2/9/2024 and evidenced the following:</p> <p>The Flowsheets dated 2/1/2024, 2/2/2023, 2/7/2024, and 2/9/2024 failed to evidence Patient #4 was assessed by the nurse within the first hour of treatment.</p> <p>The flowsheet dated 2/1/2024 documented Patient #4's EDW was 81.5 kilograms (kg), his/her pretreatment weight was 79.7 kg, and his/her post-treatment weight was 77.8 kg. The agency failed to notify the Physician the Patient was under their prescribed dry weight.</p> <p>The flowsheet dated 2/2/2024 documented Patient #4's EDW was 80.5 kg, his/her pretreatment weight was 81.6 kg, and his/her post-treatment weight was 78.4 kg. The agency failed to notify the Physician the Patient was under the prescribed dry weight.</p> <p>The flowsheet dated 2/5/2024 documented Patient #4's EDW was 80.5 kg, and his/her post-treatment weight was 73.2 kg. The agency failed to notify the Physician the Patient was under their prescribed dry weight.</p> <p>6. The clinical record review for Patient #17, start of care 5/20/2022, included a review of the dialysis treatment sheets from 2/2/2024 through 2/14/2024 and evidenced the following:</p> <p>The Flowsheets dated 2/5/2024 and 2/7/2024, failed to evidence Patient #17 was assessed by the nurse within the first hour of treatment.</p> <p>The flowsheet dated 2/2/2024 documented Patient #17's EDW was 91 kg, his/her pretreatment weight</p>		<p>including lung assessment, cardiovascular (i.e. heart sounds) and peripheral vascular assessment (edema)</p> <p><u>·Prior to discharge, the RN must review the treatment record to:</u></p> <p><u>·Confirm patient is stable for discharge.</u></p> <p>·Identify any process that could have resulted in the patient experiencing a safety event or near miss.</p> <p>·The record must be reviewed for:</p> <p><u>·Slow/fast/irregular heart rate</u></p> <p><u>·Low or high blood pressures</u></p> <p><u>·Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight</u></p> <p>·</p> <p>·Heart rate <60 or >100 addressed by the registered nurse with documentation present.</p> <p>·Blood pressures < 100 systolic or greater than 180 systolic addressed by the registered nurse with or documentation present.</p> <p>·Reported fall, and if heparin was held and MD notified.</p> <p>·Correct dialysate prescription was delivered.</p> <p><u>·The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.</u></p> <p>On 3/6/24, the Clinical Manager or designee will conduct audits on 10</p>	

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	<p>was 94.9 kg, and his/her post-treatment weight was 92.5 kg. The agency failed to notify the Physician the Patient was over their prescribed dry weight.</p> <p>The flowsheet dated 2/15/2024 documented Patient #17's EDW was 91 kg, his pretreatment weight was 94.4 kg, and his post-treatment weight was 92.2 kg. The agency failed to notify the Physician the Patient was over their prescribed dry weight.</p> <p>The flowsheet dated 2/5/2024 documented Patient #17's EDW was 91 kg, his pretreatment weight was 96.1 kg, and his post-treatment weight was 95.6 kg. The agency failed to notify the Physician the Patient was over their prescribed dry weight.</p> <p>During an interview on 2/22/2024 at 3:07 PM, RN 4 indicated the patient should be assessed in the first hour of treatment. The nurse indicated he/she notifies the Physician when patients do not meet their weight goal but sometimes it is not documented.</p> <p>7. The clinical record review for Patient #16, start of care 9/22/2014, included a review of the dialysis treatment sheets from 2/2/2024 through 2/14/2024 and evidenced the following:</p> <p>The flowsheet dated 2/6/2024 documented Patient #16's EDW was 74 kg, his/her pretreatment weight was 72.6 kg, and his/her post-treatment weight was 71 kg. The agency failed to notify the Physician the Patient was under their prescribed dry weight.</p> <p>The flowsheet dated 2/8/2024 documented Patient #16's EDW was 74 kg, his/her pretreatment weight was 76.2 kg, and his/her post-treatment weight</p>		<p>treatment sheets daily, alternating shifts, with focus on ensuring the physician is notified when the ICHD patient is below their EDW prior to treatment or when a post treatment weight is greater than/less than 1 kilogram of the ordered EDW, as well as, ensuring patients are assessed within one hour of initiation of the dialysis treatment and policies specific to recognizing and treatment of orthostatic hypotension are followed utilizing Treatment Sheet Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Treatment sheet audits will continue daily until the Statement of Deficiencies is received and will be re-evaluated at that time.</p> <p>Effective 3/21/24, Clinical Manager will conduct 10 treatment sheets daily, alternating shifts, with focus on ensuring the physician is notified when the ICHD patient is below their EDW prior to treatment or when a post treatment weight is greater than/less than 1 kilogram of the ordered EDW, as well as, ensuring patients are assessed within one hour of initiation of the dialysis treatment and policies specific to recognizing and treatment of orthostatic hypotension are followed utilizing Treatment Sheet Audit Tool for 2</p>	

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	<p>was 71.5 kg. The agency failed to notify the Physician the Patient was under their prescribed dry weight.</p> <p>The flowsheet dated 2/10/2024 documented Patient #16's EDW was 74 kg, his/her pretreatment weight was 77.5 kg, and his/her post-treatment weight was 75.4 kg. The agency failed to notify the Physician the Patient was under their prescribed dry weight.</p> <p>The Flowsheets dated 2/10/2024, 2/13/2024, and 2/17/2024, each failed to evidence Patient #16 was assessed by the nurse within the first hour of treatment.</p> <p>The flowsheet dated 2/13/2024 documented Patient #16's EDW was 74 kg, his/her pretreatment weight was 71.6 kg, and his/her post-treatment weight was 70.6 kg. The agency failed to notify the Physician the Patient was under their prescribed dry weight.</p> <p>The flowsheet dated 2/17/2024 documented Patient #16's EDW was 74 kg, his/her pretreatment weight was 72.6 kg, and his/her post-treatment weight was 705 kg. The agency failed to notify the Physician the Patient was under their prescribed dry weight.</p> <p>8. The clinical record review for Patient #14, start of care 12/27/2023, included a review of the dialysis treatment sheets from 2/1/2024 through 2/15/2024 and evidenced the following:</p> <p>The flowsheet dated 2/6/2024 indicated Patient #14's EDW was 114.5 kg, his/her pretreatment weight was 124.4 kg, and his/her post-treatment weight was 120.8 kg. The agency failed to notify the Physician the Patient was under their</p>		<p>weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p>		

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	<p>prescribed dry weight.</p> <p>The flowsheet dated 2/8/2024 indicated Patient #14's EDW was 114.5 kg, his/her pretreatment weight was 126.1 kg, and his/her post-treatment weight was 122.2 kg. The agency failed to notify the Physician the Patient was under their prescribed dry weight.</p> <p>The flowsheet dated 2/10/2024 indicated Patient #14's EDW was 114.5 kg, his/her pretreatment weight was 122.7 kg, and his/her post-treatment weight was 118.8 kg. The agency failed to notify the Physician the Patient was under their prescribed dry weight.</p> <p>The flowsheet dated 2/15/2024 indicated Patient #14's EDW was 118.8 kg, his/her pretreatment weight was 126.1 kg, and his/her post-treatment weight was 122.2 kg. The agency failed to notify the Physician the Patient was under their prescribed dry weight.</p> <p>The Flowsheet dated 2/15/2024 failed to evidence Patient #14 was assessed by the nurse within the first hour of treatment.</p> <p>During an interview on 2/21/2024 at 2:20 PM, RN 5 indicated the patient should be assessed in the first hour of treatment. The nurse indicated the Physician was notified if the patient was consistently not meeting their weight goal so the nurse could btain an order to change the weight.</p> <p>9. The clinical record review for Patient #9, start of care 04/18/2017, included a review of the dialysis treatment sheets dated 01/31/2024-02/14/2024 and evidenced the following:</p> <p>The flowsheet dated 01/31/2024 evidenced Patient #9's pre-dialysis blood pressure was 152/61 sitting</p>		<p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p>	

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	<p>and 147/58 standing and Patient's post-dialysis blood pressure was 145/68 sitting and 125/68 standing. The record failed to evidence the clinical staff implemented the policy and procedures for the treatment of orthostatic hypotension.</p> <p>The flowsheet dated 02/08/2024 evidenced Patient #9's hemodialysis start time was 6:33 AM; the documentation indicated the nurse assessment was completed at 8:55 AM.</p> <p>The flowsheet dated 02/14/2024 evidenced Patient #9's BP pre-dialysis BP was 159/68 sitting and 158/68 standing and Patient's post dialysis BP was 166/69 sitting and 123/64 standing. The record failed to evidence the clinical staff implemented the policy and procedures for the treatment of orthostatic hypotension.</p> <p>10. The clinical record review for Patient #10, start of care 11/21/2020, included a review of the dialysis treatment sheets dated 02/02/2024-02/14/2024 and evidenced the following:</p> <p>The flowsheet dated 02/02/2024 evidenced Patient #10's BP pre-dialysis was 158/92 sitting and 134/106 standing and Patient's post dialysis BP was 135/71 sitting and 105/55 standing. The record failed to evidence the clinical staff implemented the policy and procedures for the treatment of orthostatic hypotension.</p> <p>The flowsheet dated 02/07/2024 evidenced Patient #10's hemodialysis start time was 10:27 AM; the documentation indictaed the RN completed Patient's assessment at 4:04 PM, more than 5 hours after initiation of dialysis treatment.</p> <p>The flowsheet dated 02/09/2024 evidenced Patient</p>			

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V 0544 Bldg. 00	<p>#10's BP pre-dialysis was 122/47 sitting and 97/64 standing and Patient's post dialysis BP was 149/84 sitting and 117/67 standing. The record failed to evidence the clinical staff implemented the policy and procedures for the treatment of orthostatic hypotension.</p> <p>The flowsheet dated 02/12/2024 evidenced Patient #10's BP pre-dialysis was 107/51 sitting and 115/57 standing and Patient's post dialysis BP was 142/76 sitting and 120/85 standing. The record failed to evidence the clinical staff implemented the policy and procedures for the treatment of orthostatic hypotension.</p> <p>The flowsheet dated 02/14/2024 evidenced Patient #10's BP pre-dialysis was 121/67 sitting and 120/70 standing and Patient's post dialysis BP was 149/80 sitting and 110/57 standing. The record failed to evidence the clinical staff implemented the policy and procedures for the treatment of orthostatic hypotension.</p> <p>11. During an interview on 02/22/2024 at 4:26 PM, the Administrator reported the facility's policies and procedures should be followed and documented for orthostatic hypotension. The Administrator indicated RN evaluations should be completed within the 1st hour of start of hemodialysis treatment.</p> <p>494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE 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.</p>	V 0544	On 3/1/24, based on the	03/22/2024

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	<p>Based on observation, record review, and interview, the dialysis facility failed to ensure the in-center hemodialysis (ICHD) patient's dialysis prescription specific to the blood flow rate (BFR) was followed during treatment for 3 of 9 ICHD records reviewed (Patient #9, 10, 11).</p> <p>Findings include:</p> <p>1. During an observation on 2/20/24 at 10:30 AM at Station #13, Patient #11 was observed receiving dialysis treatment. The patient's observed BFR was 400 ml/min. Registered Nurse (RN) 5 was in the station at the time of the observation, reported he/she "questioned" the patient's dialysis settings, and reported he/she would speak with the technician regarding the settings.</p> <p>A clinical record review for Patient #11 included a review of the dialysis treatment sheets from 2/6/24 - 2/17/24 and evidenced the following:</p> <p>The flowsheet dated 2/13/24 indicated Patient #11's prescribed blood flow rate (BFR, the speed the dialysis machines cycles the patient's blood through the system) was 450 milliliters per minute (ml/min). During treatment, Patient #11's documented BFR was 400 ml/min. The flowsheet failed to evidenced documentation of why Patient did not receive the prescribed BFR.</p> <p>2. A clinical record review for Patient #9 included a review of the dialysis treatment sheets from 01/31/2024-02/14/2024 and evidenced the following:</p> <p>The flowsheet dated 02/05/2023 indicated Patient #9's prescribed BFR was 450 ml/min. During treatment, Patient #9's documented BFR was 400 ml/min. The documentation failed to evidence why Patient did not receive the prescribed BFR.</p>		<p>preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on the policy listed below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> -Patient Assessment and Monitoring version 4 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. -Check machine settings and measurements: <ul style="list-style-type: none"> -<u>Check prescribed blood flow is being achieved or reason is documented in medical record if unable to meet prescribed blood flow.</u> <p>On 3/6/24, the Clinical Manager or designee will conduct audits on 10 treatment sheets daily, alternating shifts, with focus on ensuring the blood flow rate is achieved and maintained throughout the dialysis treatment or justification documented utilizing Treatment</p>	

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	<p>3. A clinical record review for Patient #10, included a review of the dialysis treatment sheets from 02/02/2024 - 02/14/2024 and evidenced the following:</p> <p>The flowsheet dated 02/07/2024 indicated Patient's prescribed BFR was 500 ml/min. During treatment, Patient's documented BFR was 400 ml/min. The documentation failed to evidence why Patient did not receive their prescribed BFR.</p> <p>4. During an interview on 02/22/2024 at 4:32 PM, the Administrator indicated the BFR should be set according to the patient's prescription order. If the BFR order was not followed, the treatment sheet should evidence the reason the prescription order was not being followed, such as elevated arterial pressures on a patient with a central venous catheter.</p>		<p>Sheet Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Treatment sheet audits will continue daily until receipt of the Statement of Deficiencies and then will be re-evaluated at that time.</p> <p>Effective 3/21/24, Clinical Manager will conduct 10 treatment sheets daily, alternating shifts, with focus on ensuring the blood flow rate is achieved and maintained throughout the dialysis treatment or justification documented utilizing Treatment Sheet Audit Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p>	

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V 0545 Bldg. 00	494.90(a)(2) POC-EFFECTIVE NUTRITIONAL STATUS 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		<p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p>	

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	<p>weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.</p> <p>Based on record review and interview the dialysis center failed to provide the necessary care for patients to achieve appropriate albumin levels in 4 of 4 records reviewed of Patients below albumin goals (Patient #4, #14, #16, and #17).</p> <p>The findings include:</p> <p>1. The review of a facility policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care," dated 7/3/2023, indicated "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."</p> <p>2. The clinical record review for Patient #4 evidenced a plan of care dated 7/31/2023, with an area of focus for albumin management (the amount of protein in the blood), with a goal for albumin levels to be greater than or equal to 4.0. The document evidenced Patient #4 was not meeting his/her Albumin goal, and interventions were to "initiate/continue oral nutritional supplement per policy."</p> <p>An undated document titled "Lab Results" evidenced Patient #4 had Albumin levels on 11/23/2023 which was 3.6, on 12/18/2023 the level was 3.2, and on 02/9/24 their level was 3.7; each value was below the target level of 4.0.</p>	V 0545	<p>On 3/18/24, after receipt of the Statement of Deficiencies, the Clinical Technology Education Manager held a virtual meeting with the IDT to review, reeducate and reinforce the expectations and responsibilities of the IDT on policies:</p> <ul style="list-style-type: none"> ·Comprehensive Interdisciplinary Assessment and Plan of Care version 6 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> ·<u>The patient's Plan of Care will be guided and developed based on the findings identified in the Comprehensive Interdisciplinary Assessment.</u> ·<u>The comprehensive interdisciplinary assessment includes the following:</u> <ul style="list-style-type: none"> ·Current health status including co-morbid conditions · ·Evaluation of appropriateness of dialysis prescription (including at least a monthly Kt/V or equivalent measure on HD patients or at least every 4 months on PD patients by calculating a delivered wKt/V or equivalent measure) ·Blood pressure and fluid management needs ·<u>Prescribed lab testing,</u> immunization history and 	04/05/2024

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	<p>3. The clinical record review for Patient #14 evidenced a plan of care dated 12/27/2023 that evidenced an area of focus for albumin management with a goal for albumin levels to be greater than or equal to 4.0; the document evidenced Patient #14 was not meeting their Albumin goal, and interventions were to "initiate/continue oral nutritional supplement per policy."</p> <p>An undated document titled "Lab Results" evidenced Patient #4 had Albumin levels on 11/27/2023 was 2.7 which was below the target level of 4.0.</p> <p>4. The clinical record review for Patient #16 evidenced a plan of care dated 12/27/2023 with an area of focus for albumin management with a goal for albumin levels to be greater than or equal to 4.0; the document evidenced Patient #16 was not meeting his/her Albumin goal, and interventions were to "initiate/continue oral nutritional supplement per policy."</p> <p>An undated document titled "Lab Results" evidenced Patient #16 had Albumin levels on 11/20/2023 and was 2.6, on 12/26/2023 the level was 2.7, on 1/2/2024 the level was 3.0 and 2/10/24 the level was 2.6. Each valuse was below the target level of 4.0.</p> <p>During an interview on 2/22/2024, Clinic Manager 2 indicated the interventions are chosen from a list and they are working with the patient to reach his/her albumin goals.</p> <p>5. The clinical record review for Patient #17 evidenced a plan of care dated 4/28/2023 with an area of focus for albumin management with a goal</p>		<p>medication history</p> <ul style="list-style-type: none"> ·Evaluations of factors associated with anemia and potential treatment plan for anemia, including administration of erythropoiesis-stimulating agents. ·<u>Evaluation of factors associated with renal bone disease.</u> ·<u>Evaluation of nutritional status by a qualified dietitian</u> ·Evaluation of psychosocial needs by a qualified social worker ·Evaluation of dialysis access types and maintenance ·Evaluation of the patient abilities, interest, preferences, and goals, including the desired level of participation in the dialysis care process, the preferred modality and setting and the patient expectations for care outcomes ·Evaluation of suitability for a transplant referral ·Evaluation of family and other support systems ·Evaluation of current patient physical activity level ·Evaluation of referral to vocational and physical rehabilitation services ·<u>The patient plan of care will be developed from the findings gathered in the CIA. The IDT members are expected to interact and share information from the comprehensive assessment to facilitate the development of the plan of care.</u> ·<u>Problems electronically</u> 	

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	<p>for albumin levels to be greater than or equal to 4.0; the document evidenced Patient #17 was not meeting his/her Albumin goal, and interventions were to "initiate/continue oral nutritional supplement per policy."</p> <p>An undated document titled "Lab Results" evidenced Patient #17 had Albumin levels on 11/19/2023 and the level was 2.6; on 12/6/2023 the level was 2.8 and on 01/15/2024 the level was 2.6. Each value was below the target level of 4.0.</p> <p>During an interview on 2/21/2024 at 3:02 PM, Dietitian 1 indicated Patient #17 did not like a lot of the supplements so Dietician was educating Patient on better protein sources and trying to find a supplement he/she will use.</p>		<p><u>generated from the CIA must be reviewed by the IDT and determine whether the problem will be included in the patient's POC.</u></p> <p><u>Problems electronically generated from the CIA and not included in the POC, must have a reason documented as to why the problem wasn't included such as determining that the condition is chronic.</u></p> <p><u>·The Plan of Care must include measurable and expected outcomes and an estimated timetable to achieve these outcomes.</u></p> <p><u>·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 timeframe:</u></p> <p><u>·The Interdisciplinary team must adjust the patient's Plan of Care and document changes made to the POC.</u></p> <p><u>·Implement the Plan of Care changes to address the identified issues.</u></p> <p>Effective 3/21/24, the Clinical Manager will conduct a review of all care plans due within the month to ensure the necessary care for patients to achieve appropriate albumin levels is provided. Patients' stability status will be reviewed monthly, and the plan of care completed at least annually, minimally, to review and</p>	

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			<p>update the plan of care. Monitoring for continued compliance will be done monthly through the ePOC Dashboard and any noncompliance will be noted in the monthly QAI meeting minutes.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written</p>	

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V 0547 Bldg. 00	<p>494.90(a)(4) POC-MANAGE ANEMIA/H/H MEASURED Q MO</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>Based on record review and interview the dialysis facility failed to provide the necessary care for patients to achieve appropriate hemoglobin level for 1 of 1 Patient that was not meeting their anemia goals (Patients #14).</p> <p>The findings include:</p> <p>The review of a facility policy titled Comprehensive Interdisciplinary Assessment and Plan of Care," dated 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</p>	V 0547	<p>to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 4/5/24.</p> <p>On 3/18/24, after receipt of the Statement of Deficiencies, the Clinical Technology Education Manager held a virtual meeting with the IDT to review, reeducate and reinforce the expectations and responsibilities of the IDT on policies:</p> <ul style="list-style-type: none"> -Comprehensive Interdisciplinary Assessment and Plan of Care version 6 <p>Emphasis was placed on: <u>·The patient's Plan of Care will be guided and developed based</u></p>	04/05/2024

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	<p>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."</p> <p>The clinical record review for Patient #14 evidenced a plan of care {POC} dated 01/29/2024 with an area of focus for anemia management, with a goal for hemoglobin (Hgb) levels to be 10-11. The POC indicated Patient #14 met the goal of 10-11. The POC was not updated to reflect the current POC goal.</p> <p>An undated document titled "Lab Results" evidenced the Patient #14 had hemoglobin levels on 1/4/2024 was 8.3, 1/6/2024 was 8.7, 1/9/2024 was 9, 1/23/2024 was 6.8, 1/30/2024 was 7.0, and 2/6/2024 was 7.2, all of which were below the target level of 10-11.</p> <p>During an interview on 02/20/2024 at 2:02 PM, Registered Nurse (RN) 4 indicated Patient #14 was receiving Venofer and Mircera (medications given to treat low Hemoglobin in dialysis patients). The nurse indicated Patient's physician was aware of the low hemoglobin; indicated Patient hemoglobin goal was met in December of 2022. RN 4 indicated their EMR does not permit them to accurately update Patient's POC and that the current POC does not reveal that the Patient is below their hemoglobin goal of 10 - 11 and the POC does not include the interventions in place to achieve this goal.</p>		<p><u>on the findings identified in the Comprehensive Interdisciplinary Assessment.</u></p> <p><u>·The comprehensive interdisciplinary assessment includes the following:</u></p> <ul style="list-style-type: none"> ·Current health status including co-morbid conditions · ·Evaluation of appropriateness of dialysis prescription (including at least a monthly Kt/V or equivalent measure on HD patients or at least every 4 months on PD patients by calculating a delivered wKt/V or equivalent measure) ·Blood pressure and fluid management needs <u>·Prescribed lab testing,</u> immunization history and medication history <u>·Evaluations of factors associated with anemia and potential treatment plan for anemia,</u> including administration of erythropoiesis-stimulating agents. ·Evaluation of factors associated with renal bone disease. ·Evaluation of nutritional status by a qualified dietitian ·Evaluation of psychosocial needs by a qualified social worker ·Evaluation of dialysis access types and maintenance ·Evaluation of the patient abilities, interest, preferences, and goals, including the desired level of participation in the dialysis care process, the preferred modality 	

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			<p>and setting and the patient expectations for care outcomes</p> <ul style="list-style-type: none"> ·Evaluation of suitability for a transplant referral ·Evaluation of family and other support systems ·Evaluation of current patient physical activity level ·Evaluation of referral to vocational and physical rehabilitation services <p><u>·The patient plan of care will be developed from the findings gathered in the CIA. The IDT members are expected to interact and share information from the comprehensive assessment to facilitate the development of the plan of care.</u></p> <p><u>·Problems electronically generated from the CIA must be reviewed by the IDT and determine whether the problem will be included in the patient's POC. Problems electronically generated from the CIA and not included in the POC, must have a reason documented as to why the problem wasn't included such as determining that the condition is chronic.</u></p> <p><u>·The Plan of Care must include measurable and expected outcomes and an estimated timetable to achieve these outcomes.</u></p> <p><u>·If the patient specific expected outcome as determined by the attending physician, IDT and patient for the Plan of Care is not</u></p>	

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			<p><u>achieved within the identified timeframe:</u></p> <ul style="list-style-type: none"> <u>·The Interdisciplinary team must adjust the patient's Plan of Care and document changes made to the POC.</u> <u>·Implement the Plan of Care changes to address the identified issues.</u> <p>Effective 3/21/24, the Clinical Manager will conduct a review of all care plans due within the month to ensure the necessary care for patients to achieve appropriate hemoglobin levels is provided. Patients' stability status will be reviewed monthly, and the plan of care completed at least annually, at a minimum, to review and update the plan of care. Monitoring for continued compliance will be done monthly through the ePOC Dashboard and any noncompliance will be noted in the monthly QAI meeting minutes.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p>	

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V 0556 Bldg. 00	494.90(b)(1) POC-COMPLETED/SIGNED BY IDT & PT The patient's plan of care must- (i) Be completed by the interdisciplinary team, including the patient if the patient desires; and (ii) Be signed by the team members,		The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 4/5/24.		

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	<p>including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.</p> <p>Based on record review and interview, the dialysis facility failed to ensure the plan of care was reviewed and signed by the patient, and if the patient declined to sign, this would be indicated on the plan of care for 9 of 9 active in-center hemodialysis records reviewed (Patient #3, 7, 9, 10, 11, 14, 15, 16, and 17).</p> <p>Findings include:</p> <p>1. A review of facility policy #45283 titled "Comprehensive Interdisciplinary Assessment and Plan of Care," dated 07/03/23, indicated the patient must sign the plan of care "to acknowledge the information in the plan." If the patient declined to sign the plan of care, the facility should document the "reason for refusal."</p> <p>2. The clinical record for Patient #3's evidenced a plan of care dated 3/28/23; the plan of care failed to evidence either the Patient signed the plan of care or had declined to sign.</p> <p>During an interview with Patient #3 on 2/16/24 beginning at 10:55 AM, the patient reported since receiving dialysis at the facility in 2021, he/she had not been notified by the facility of an Interdisciplinary Team (IDT) meeting to review Patient's plan of care nor had the facility reviewed the patient's plan of care with him/her. Patient reported he/she had not been asked by the facility to sign a plan of care.</p> <p>3. The review of Patient #7's medical record</p>	V 0556	<p>On 3/18/24, after receipt of the Statement of Deficiencies, the Clinical Technology Education Manager held a virtual meeting with the IDT to review, reeducate and reinforce the expectations and responsibilities of the IDT on policies:</p> <ul style="list-style-type: none"> -Comprehensive Interdisciplinary Assessment and Plan of Care version 6 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -Provide appropriate patient education to enable the patient to participate in the development of the Plan of Care. -Encourage both patient and family to participate in the Plan of Care discussions in whatever format the facility and attending physician develop. -<u>Notify the patient in writing of the time and date of the Plan of Care review.</u> -Review expectation for participation in the Plan of Care with each patient. -Review this expectation again when Rights and Responsibilities are reviewed. -If the patient and or designee is unable or unwilling to attend the Plan of Care meeting or if the 	04/05/2024
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	<p>evidenced the IDG last completed a plan of care meeting to review the patient's plan of care on 12/19/22. The plan of care failed to evidence either Patient signed the plan of care or had declined to sign.</p> <p>4. A review of Patient #11's medical record included a plan of care dated 3/23/23. The plan of care failed to evidence either Patient signed the plan of care or had declined to sign.</p> <p>During an interview with Patient #11 on 2/22/24 beginning at 12:50 PM, the patient reported facility staff had reviewed Patient's plan of care with him/her but could not recall if he/she signed it.</p> <p>5. A review of Patient #9's medical record included a plan of care dated 1/29/24. The plan of care failed to evidence Patient signed the plan of care nor that they had declined to sign.</p> <p>6. A review of Patient #10's medical record included a plan of care dated 7/21/23. The plan of care failed to evidence either Patient signed the plan of care or had declined to sign.</p> <p>7. A review of Patient #14's medical record included a plan of care dated 12/27/23. The plan of care failed to evidence either Patient signed the plan of care or had declined to sign.</p> <p>8. A review of Patient #15's medical record included a plan of care dated 1/29/24. The plan of care failed to evidence either Patient signed the plan of care or had declined to sign.</p> <p>9. A review of Patient #16's medical record included a plan of care dated 4/28/23. The plan of care failed to evidence either Patient signed the plan of care or had declined to sign.</p>		<p>patient attends via telehealth/virtual:</p> <p><u>·The registered nurse may review the Plan of Care as developed by the IDT at the meeting with the patient and obtain the patient's signature and any comments.</u></p> <p><u>·If the patient is not physically present at the meeting or is remote at the time of review, a signature may be obtained later.</u></p> <p><u>·The patient's level of participation is determined by the patient. The patient must sign the plan of care meant to acknowledge the information in the plan. If the patient chooses not to sign their plan of care, the reason for refusal must be documented in the patient's medical record.</u></p> <p>Effective 3/21/24, the Clinical Manager will conduct a review of all care plans completed within the month to ensure the plan of care is reviewed and signed by the patient, and if the patient declined to sign the plan of care, the reason of refusal is documented in the patient's medical record. Patients' stability status will be reviewed monthly, and the plan of care completed at least annually, at a minimum, to review and update the plan of care. Monitoring for continued compliance will be done monthly through the ePOC Dashboard and any</p>	

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	<p>10. A review of Patient #17's medical record included a plan of care dated 9/25/23. The plan of care failed to evidence either Patient signed the plan of care or had declined to sign.</p> <p>11. During an interview on 2/20/2024 at 10:03 AM, the Administrator indicated the facility did not have any of the above patients' signed plans of care. Administrator reported there was a new secretary and he/she sent all the signed plans of care to Iron Mountain (place for medical document storage).</p>		<p>noncompliance will be noted in the monthly QAI meeting minutes.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p>	

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V 0715 Bldg. 00	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must-</p> <p>(2) Ensure that-</p> <p>(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers;</p> <p>Based on observation, record review, and interview, the Medical Director failed to ensure all policies and procedures were followed by staff for 4 of 4 observations of staff performing cannulation of an arteriovenous (AV) fistula (Patient Care Technicians (PCT) 2, 3, 7, 9)</p> <p>Findings include:</p> <p>1. The review of facility policy #45178 titled "Access Assessment and Cannulation," dated 07/05/2022, indicated prior to treatment, the patient should be asked to wash his or her access area with soap. Staff should wash the access area if the patient was unable to clean their access. After assessing the fistula site by listening with a stethoscope for a bruit and feeling the site for a thrill, staff should remove his/her gloves, perform hand hygiene, and don new gloves. The policy indicated when disinfecting the fistula cannulation site with a 70% alcohol pad, povidone</p>	V 0715	<p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 4/5/24.</p> <p>On 3/1/24, based on the preliminary findings noted in the exit conference with the State Agency, the Education Coordinator met with staff to provide education and reinforce the expectations and responsibilities of staff on the policy listed below.</p> <p>On 3/15/24, after receipt of the Statement of Deficiencies, the Education Coordinator met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> ·Access Assessment and Cannulation version 3 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> ·Prior to treatment, ask the patient to wash the access area 	03/22/2024

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	<p>iodine pad, or 2% chlorhexidine and 70% alcohol pad, staff should clean the site for 30 seconds and allow to dry prior to cannulation. Staff should not touch the cannulation sites after disinfection.</p> <p>2. During an observation at Station #7 on 2/19/24 beginning at 9:37 AM, PCT 2 was observed initiating Patient #24's dialysis by accessing an arterial-venous (AV) fistula. PCT 2 was observed cleaning the patient's first cannulation site using a 70% alcohol pad for 20 seconds then cleaned the second cannulation site using a 70% alcohol pad for 23 seconds.</p> <p>3. During an observation at Station #17 on 2/19/24 beginning at 9:45 AM, PCT 7 was observed initiating Patient #25's dialysis by accessing an AV fistula. PCT 7 was observed cleaning the patient's first cannulation site using a 70% alcohol pad for 10 seconds then cleaned the second site using a 70% alcohol pad for 3 seconds. PCT 7 felt for a thrill over the cleaned sites, removed his/her gloves, then left the treatment floor. At 9:48 AM, PCT 7 returned to the treatment floor with his/her stethoscope, entered Station #17, auscultated and felt Patient #25's fistula sites for a bruit and thrill, then cannulated the first site. PCT 7 attempted to cannulate Patient #25's second fistula site but was unsuccessful. The technician failed to clean the cannulation site after leaving the station and reassessing the site.</p> <p>During an interview with PCT 7 on 2/20/24 beginning at 9:59 AM, the technician reported each AV fistula cannulation site should be cleaned for 30 seconds with alcohol or betadine. PCT 7 reported if the process of initiating dialysis is interrupted, the access sites should be cleaned again prior to cannulation. The technician stated independent patients should clean the AV fistula</p>		<p>with soap per hand hygiene procedure. Wash access (per above) if patients are unable to clean their access.</p> <ul style="list-style-type: none"> ·Remove gloves and perform hand hygiene. Don new gloves. ·Disinfect cannulation site as follows: <ul style="list-style-type: none"> ·70% isopropyl alcohol pad: Using gentle friction, clean the access site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds and allow to dry before cannulating. ·Perform skin antisepsis on one site at a time, allow to dry and then cannulate. Do not touch cannulation sites after skin disinfection. <p>On 3/7/24, the Clinical Manager implemented daily audits with focus on ensuring staff follow policy and procedure for performing cannulation of an AV fistula as required utilizing the Clinic Audit Tool. Findings from the audits will be shared with DPC staff in the form of a daily huddle and documented on an in-service form. Audits will continue daily until receipt of the Statement of Deficiencies and then will be re-evaluated at that time.</p> <p>Effective 3/21/24, Clinical Manager will conduct daily audits with focus on ensuring staff follow policy and procedure for performing</p>	

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	<p>site with soap and water at the designated sink upon arrival to the ICHD treatment floor and staff should clean the fistula sites with soap and water for dependent patients prior to beginning cannulation procedures.</p> <p>4. During an observation at Station #10 on 2/19/24 beginning at 11:20 AM, PCT 3 was observed bringing Patient #39 into the treatment area via wheelchair and transferring Patient into the chair via Hoyer lift. The technician began to initiate Patient's dialysis by accessing an AV fistula, failing to clean the dependent patient's site prior. PCT 3 auscultated the fistula site with a stethoscope, prepared supplies, and cleaned the first cannulation site with a disinfectant wipe for 10 seconds. PCT 3 failed to change gloves and perform hand hygiene prior to disinfecting the cannulation site. The technician allowed the area to dry for 4 seconds prior to cannulation. PCT 3 left the station to assist with another patient. At 11:25 AM, PCT 3 returned to Station #10 and cleaned Patient #39's second cannulation site with a disinfectant wipe for 8 seconds.</p> <p>During an interview with PCT 3 on 2/19/24 beginning at 4:04 PM, the technician reported a dependent patient's AV fistula site should be cleansed with Except disinfectant prior to initiating cannulation procedures. PCT 3 reported after assessing the site for a thrill and bruit, each cannulation site should be cleaned for 30 seconds with Betadine or alcohol. The technician reported the disinfectant should be allowed to dry prior to cannulating.</p> <p>5. During an observation at Station #3 on 2/19/24 beginning at 11:30 AM, PCT 7 was observed walking with Patient #30 into the treatment area, obtaining the patient's pre-treatment weight, and</p>		<p>cannulation of an AV fistula as required utilizing Clinic Audit Tool for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.</p> <p>The Facility Administrator is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p> <p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed</p>	

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	<p>walking with the patient to Station #3. The technician failed to remind the patient to clean his/her AV fistula site with soap and water prior to entering the station. At 11:46 AM, PCT 9 auscultated Patient's AV fistula site, cleaned the first site with a disinfectant wipe for 6 seconds, and then cleaned the second site with a disinfectant wipe for 9 seconds. PCT 9 failed to clean the patient's fistula site with soap and water and failed to change gloves and perform hand hygiene prior to disinfecting the cannulation site. After disinfecting the sites, PCT 9 felt the first access site for a thrill twice prior to cannulation.</p> <p>During an interview with PCT 9 on 2/19/24 beginning at 3:59 PM, the technician reported when cannulating an AV fistula site, each site should be cleaned for 30 seconds with a disinfectant wipe. PCT 9 reported independent patients may clean their AV fistula site prior to arriving at the dialysis facility. If a patient is dependent, the technician would clean the fistula site with soap and water prior to initiating cannulation procedures.</p> <p>6. During an interview with Administrator and Clinic Manager 2 on 2/20/24 beginning at 4:20 PM, the clinic manager reported the patient should clean his/her AV fistula site with soap and water upon entering the ICHD treatment floor. Clinic Manager 2 stated the patient cleaning the site prior to arrival at the facility was not acceptable. If the patient was unable to wash their own fistula site, staff should do perform the cleaning at the station prior to initiating cannulation procedures. Clinic Manager 2 also reported each fistula site should be disinfected for 30 seconds prior to cannulation.</p>		<p>in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 3/22/24.</p>	

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V 0767 Bldg. 00	<p>494.180(f)(4) GOV-INVOL DISCHARGE PROCESS REQUIREMENTS</p> <p>The medical director ensures that no patient is discharged or transferred from the facility unless -</p> <p>(4) The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient's interdisciplinary team-</p> <p>(i) Documents the reassessments, ongoing problems(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record;</p> <p>(ii) Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge;</p> <p>(iii) Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility;</p> <p>(iv) Contacts another facility, attempts to place the patient there, and documents that effort; and</p> <p>(v) Notifies the State survey agency of the involuntary transfer or discharge.</p> <p>(5) In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.</p> <p>Based on record review and interview, the dialysis facility's Governing Body failed to oversee the involuntary discharge of an in-center hemodialysis patient and ensure all staff followed</p>	V 0767	On 2/20/24, the Clinical Manager and Manager of Social Work held a staff meeting to provide education and to reinforce the expectations and responsibilities	04/05/2024	

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	<p>all policies and procedures specific to involuntary discharge for 1 of 1 patient in which the facility had initiated an involuntary discharge in February 2024 (Patient #3).</p> <p>Findings include:</p> <p>1. The policy titled "Routine and Involuntary Patient Discharge," dated 9/04/19, indicated the Governing Body must ensure all staff followed the facility's patient discharge and transfer policies and procedures. The medical director was to ensure no patient was involuntarily discharged unless "the facility can no longer meet the patient's documented medical needs ... the patient's behavior is deemed disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired." The policy indicated a patient at risk for involuntary discharge must be reassessed by the interdisciplinary team (IDT) and the IDT should document in the patient's medical record "the reassessments, ongoing problem(s), and effort(s) made to resolve the problem(s)." For involuntary discharges due to disruptive or abusive behavior, the facility should consult the "Disruptive Patient Behavior and Use of Behavioral Agreement" policy "at the first sign of disruptive or abusive behavior that does not rise to the level of a severe and immediate threat to the health and safety of others." The policy indicated prior to an involuntary discharge, "there must be evidence in the patient's medical record of the IDT's efforts to help the patient resolve any conflict or psychological issues contributing to the behavior." For involuntary discharges due to the facility's inability to meet the patient's needs, the facility should consider "all reasonable alternatives for continuing to provide care to the</p>		<p>of the facility staff on the policies below.</p> <p>On 3/18/24 & 3/19/24, after receipt of the Statement of Deficiencies, the Social Work Managers met with staff to reeducate and reinforce the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> -Routine and Involuntary Patient Discharge version 4 -Routine and Involuntary Patient Discharge Procedure version 3 -Disruptive Patient Behavior and Use of Behavioral Agreement version 2 -Disruptive Patient Behavior and Use of Behavioral Agreement Procedure version 2 <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> -The Medical Director shall ensure that <u>no patient is involuntarily discharged, or transferred from the facility unless:</u> -The patient or payer no longer reimburses the facility for the ordered services, the payer materially reduces its established reimbursement to the facility, which the facility deems nonpayment for the ordered services, or the facility is unable to verify the actual rate of payment with the patient's commercial payer prior to the patient's admission and the payer 	

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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE GARY	STREET ADDRESS, CITY, STATE, ZIP COD 3290 GRANT ST GARY, IN 46408
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	<p>patient in the facility." The facility should conduct a meeting between the IDT and the patient and/or patient's representative "to discuss the patient's current status and barriers to providing a safe treatment environment for the patient" and discuss other treatment modalities and other locations that provide dialysis, such as a nursing home. The patient's medical record should include "documentation of all efforts to manage the patient's care and outcomes as well as all discussions with the patient and his/her representative."</p> <p>2. The policy titled "Disruptive Patient Behavior and Use of Behavioral Agreement," dated 4/04/12, indicated a patient at risk for involuntary discharge must be considered 'unstable' and reassessed by the interdisciplinary team (IDT). The patient's plan of care should be revised "to demonstrate interventions or resources agreed upon by the patient or determined necessary by the interdisciplinary team to resolve barriers or other issues contributing to the disruptive behavior." The policy indicated a behavioral agreement "should be considered" when "the patient's behavior has escalated beyond the ability to be handled by an informal resolution process ... individual consultation with the patient's attending physician, clinical manager, [social worker] or a team meeting, patient/family meeting or patient education has not resulted in positive improvement in the patient's behavior ... the patient's behavior has potential to harm the patient or others ... the patient's behavior will potentially result in termination of dialysis services if not modified or stopped." The behavioral agreement was to "define what responsibilities or expectations the patient will need to meet to continue to receive services in the facility" and should indicate "consequences of</p>		<p>subsequently reimburses the Facility at an insufficient rate relative to historical commercial insurer payment rate.</p> <ul style="list-style-type: none"> ·The facility ceases to operate. ·<u>The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs.</u> ·<u>The patient's behavior is deemed disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired.</u> <p>·The patient's behavior is an immediate and severe threat that is deemed dangerous to the health and safety of others (Examples: A patient with a gun or knife or who is making credible threats of physical harm).</p> <ul style="list-style-type: none"> ·The patient's attending physician or physician group has notified the patient that medical services are being terminated and there is no other attending physician at the facility available or willing to accept the patient. ·Patients shall be informed of discharge and transfer policies and procedures as part of the patient education process and as necessary. <u>The facility's Governing Body shall ensure that all staff follow the facility's discharge and transfer policies and procedures.</u> ·<u>Facility staff should consult the</u> 	

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	<p>continued disruptive behavior," including "possible discharge." The policy indicated once a behavioral agreement was implemented, the IDT would review the "progress of a patient's Behavioral Agreements on a monthly basis until the patient's behavior is either resolved, stabilized, or worsens to the extent that involuntary discharge is considered." The policy defined verbal abuse as "use of words, written or spoken, that demean, insult, belittle or degrade a person."</p> <p>3. During an interview with Patient #3 on 2/14/24 beginning at 9:09 AM, Patient reported that on 02/09/24, Patient Care Technician (PCT) 1 scratched and slapped him/her while setting up Patient's dialysis treatment. Patient reported he/she had previously filed a complaint with the facility against PCT 1, so the technician was only supposed to "push the buttons" on the patient's dialysis machine and not provide direct patient care, however on 2/09/24, the facility was short-staffed and PCT 1 had to set up the patient's dialysis treatment. Administrator came to Patient's chairside shortly after to discuss the alleged incident. Patient #3 reported during his/her conversation with Administrator, the employee told Patient he/she was aware Patient had filed complaints before with the SA. Patient #3 reported Administrator denied the alleged incident between the Patient #3 and PCT 1 occurred and Patient asked how Administrator would like if their family member was being assaulted? Patient #3 reported Administrator became angry at Patient's comment regarding his/her family member. While leaving the treatment floor, Administrator yelled "take [him/her] off [the dialysis treatment]." Patient #3 reported on 2/12/24, he/she was notified by the facility he/she was being involuntarily discharged due to being "violent, aggressive" and "hitting, spitting."</p>		<p><u>Disruptive Patient Behavior and Use of Behavioral Agreement policy at the first sign of disruptive or abusive behavior that does not rise to the level of a severe and immediate threat to the health and safety of others. Before involuntary transfer or discharge can occur, there must be evidence in the patient's medical record of the IDT's efforts to help the patient resolve any conflict or psychological issues contributing to the behavior.</u></p> <p>Effective 3/21/24, the Interdisciplinary Team will review progress of a patient's Behavioral Agreement monthly at their unstable plan of care meeting until the patient's behavior is either resolved, stabilized, or worsens to the extent that involuntary discharge is considered. Patients' stability status will be reviewed monthly and the plan of care at least annually, at a minimum, to review and update the plan of care.</p> <p>The Medical Director will review each month at the QAI Committee meeting.</p> <p>The Facility Administrator is responsible for reviewing, analyzing, and trending all data and monitoring results as related to this Plan of Correction prior to presenting to the QAI Committee monthly.</p>	

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	<p>The review of an audio recording of Patient #3 and Administrator's interaction on 02/09/24 evidenced during the interaction, Administrator stated he/she was aware Patient had made complaints to the SA. When Patient denied he/she had filed complaints with the SA, Administrator stated "yes you have ... I know everything." Administrator stated the alleged assault by PCT 1 did not occur, as if it had, the technician would be "in a police car." Patient #3 stated PCT 1 wanted to "beat the garbage out of me ... we could have had a fight. I've had people assault me before." Administrator responded, "And you beat them up." Patient denied saying he/she had beat anyone up and patient hoped "somebody beat [the Administrator's family member] up like [PCT 1]'s doing." Administrator stated his/her family member was dead and Patient #3 responded stating "And maybe that's why." Administrator was heard yelling "So my [family member] is dead and [Patient #3] thinks [the family member]'s dead because [the family member] got beat up. You have lost your mind." Additional staff members could be heard coming to the chairside and telling Administrator to walk away. Administrator could then be heard yelling in the distance "take [Patient #3] off [his/her dialysis treatment]."</p> <p>During an interview with Employee H on 02/14/24 beginning at 11:24 AM, the employee reported on 02/9/24, Patient #3 called the local police regarding the alleged assault by PCT 1. The employee reported a police officer and ambulance came to the facility and spoke with Patient at his/her chairside. Employee H reported the police officer also spoke with PCT 1, other employees including him/herself, and other patients, regarding the alleged incident.</p>		<p>The Facility Administrator is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.</p> <p>Completion 4/5/24.</p>	

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	<p>During an interview with Medical Director on 2/14/24 beginning at 1:25 PM, the physician reported he/she attempted to speak with Patient #3 on 02/12/24 regarding the incidents on 2/09/24 but Patient refused. Medical Director reported the facility had issues with Patient's behaviors in the past, but the physician was not aware of Patient being verbally or physically abusive towards staff. The physician had met with Patient #3 and Family Member A "on several occasions" to discuss Patient's behaviors within the past 6 months, however the meetings "didn't resolve anything." Medical Director reported he/she did not document the meetings. Medical Director was not aware of the facility enacting a behavioral agreement with Patient #3 prior to 02/12/24.</p> <p>During an interview with Medical Social Worker (MSW) 1 on 02/14/24 beginning at 3:20 PM, the social worker reported the facility had concerns with Patient #3's inappropriate behaviors in past. The social worker reported the facility IDT had tried to have meetings with Patient #3 regarding his/her behavior, but Patient would not come to the meetings. The social worker reported he/she did not document attempts to conduct meetings as the clinic manager was responsible for setting up these meetings. MSW 1 reported the facility had not made a behavioral agreement with Patient #3 prior to 02/12/24 because the staff hoped Patient's behavior would improve.</p> <p>During an interview with Administrator on 02/14/24 beginning at 3:54 PM, Administrator reported the facility had tried previously to enact a behavioral contract with Patient #3, however Patient did not attend the IDT meeting; Administrator could not recall when this occurred. Administrator reported on 02/09/24, a local police</p>			

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	<p>officer came to the facility after being called by Patient #3. Per Administrator, the police officer informed the facility staff he/she would not file a report as Patient's allegations were unsubstantiated. Administrator reported he/she spoke with Patient #3 at his/her chairside regarding the alleged incident and Patient became "snappy," stated he/she should have hit PCT 1, and repeatedly brought up Administrator's deceased family member. Administrator reported Patient's "volume started increasing" and 2 employees came over to the chairside and advised Administrator to walk away. The employee reported as he/she was leaving the treatment floor, Administrator advised facility staff to end Patient #3's treatment early due to Patient saying he/she "should have" hit PCT 1. Later that day, Administrator met with MSW 1 and Corporate Employees 1 and 2 to discuss the incident. Administrator reported during the meeting, the facility and corporate staff determined Patient #3 was to be involuntarily discharged. Administrator reported during a meeting with Patient, Medical Director, MSW 1, Corporate Employee 2, and Administrator, Patient #3 was notified of the involuntary discharge and initiation of a behavioral agreement.</p> <p>The medical record evidenced the IDT last held a plan of care meeting for Patient #3 on 3/28/23. The plan of care failed to evidence the IDT noted any disruptive or abusive behaviors by Patient towards staff and/or other patients.</p> <p>During a follow-up interview with Administrator on 2/15/24 at 8:45 AM, Administrator reported Patient #3's plan of care was due to be updated in February 2024 and facility was waiting on all members of the interdisciplinary team (IDT) to update his/her portions of the comprehensive</p>			

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	<p>assessment before it could hold a Plan of Care meeting.</p> <p>The record included a "Patient Discharge Letter," dated 02/12/24, which indicated Patient was to be involuntarily discharged, effective 3/12/24, for "behavior that is disruptive and abusive to the extent that it impairs the delivery of care to you or the ability of the facility to operate effectively; the facility can no longer meet your documented needs." The letter indicated on 02/09/24, Patient #3 called the local police department "because [he/she] stated a PCT tried to assault [him/her]. When the staff attempted to talk to [patient, he/she] became verbally aggressive, loud, and disruptive and stated [he/she] should have hit the PCT."</p> <p>The record included a "Behavioral Agreement" for Patient #3, signed by Clinic Manager 2 and Medical Director on 02/12/24. The behavioral agreement indicated Patient needed to "be considerate of other patients and staff," including not using "swear words, threats, or other foul language to degrade, hurt, or be disrespectful to staff or other patients" and "not acting in a way that makes other people in the clinic uncomfortable or afraid for their safety, such as kicking, hitting, threatening, cursing, and yelling." The behavioral agreement was to be "reviewed by the Clinic Manager on a monthly basis" with Patient. The behavioral agreement failed to evidence the patient's impending involuntary discharge.</p> <p>The record indicated prior to Patient #3's involuntary discharge notification on 02/12/24, the last documented nursing comprehensive assessment was completed on 4/05/23.</p>			

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	<p>The record included a Clinical Note documented on 11/16/22 at 10:30 by MSW 1. The note indicated the social worker spoke with Patient #3 and Family Member A regarding "issues" Patient #3 was having at the facility. MSW 1 noted Patient #3 and Family Member A had multiple complaints about the facility, including "problems with a PCT" and "numerous complaints against the staff." The note indicated MSW 1 informed the clinic manager of Patient's complaints. The social worker noted the clinic manager had stated several patients had complained about Patient #3 and the patient's "behaviors. [Patient #3] was observed throwing a blood pressure cuff and yelling and hitting dialysis chair."</p> <p>The record included a Progress Note documented on 11/19/22 by MSW 1. The note indicated ESRD Physician 1, Former Clinic Manager B, and MSW 1 met with Patient #3 and Family Member A. The note indicated Patient had several complaints regarding his/her care and facility staff. ESRD Physician 1 summarized Patient's treatment and "problems with low blood pressure." The physician suggested Patient #3 consider an alternative treatment modality. MSW 1 documented Former Clinic Manager B was to "talk to staff for their version of incident." The record failed to evidence details regarding the "incident" to which the note referred.</p> <p>The record included a Progress Note documented on 11/30/22 by MSW 1. The note indicated Administrator and MSW 1 met with Patient #3 to discuss "current incident." Patient #3 reported he/she felt like the facility staff did not like him/her and Patient had "issues regarding [his/her] care." MSW 1 documented the facility provided Patient #3 with educational materials on alternative treatment modalities, Patient's rights and</p>			

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	<p>responsibilities, and "Thriving without Fear/Managing Retaliation." The record failed to evidence details regarding the "incident" mentioned, any follow-up by facility staff regarding the 11/19/22 or 11/30/22 meetings with Patient, nor Patient's responses to the 11/19/22 and/or 11/30/22 meetings.</p> <p>The record included a Clinical Note documented on 2/13/23 by Administrator. The note indicated Administrator spoke with Patient #3 and Family Member A regarding Patient and family member's multiple concerns. Family Member A reported he/she had overheard a technician telling Patient #3 to "just get in the damn chair." Administrator asked Patient if he/she wanted to transfer to another dialysis unit and Patient declined. The note indicated Patient #3 and Family Member A "began to get very agitated and rude" to Administrator during the conversation. Administrator documented he/she advised Patient #3 to "practice patience, be kind, and respectful to all staff at all times, as the PCT today that took care of Patient was crying and upset by the way [he/she] was treated by Patient." Patient reported he/she was not rude nor yelled at the employee. Administrator documented after the discussion with Patient #3 and Family Member A, the technician reported he/she feared providing care to Patient #3 due to Patient being "rude and condescending and [the technician was] scared to make a mistake as [he/she] might be reported to leadership." The record failed to evidence any follow-up nor documenttion of Patient's response to the meeting, including if there was any improvement to Patient's reported behaviors.</p> <p>The review of the facility's adverse event log evidenced an event documented on 3/22/23 by PCT 1. The event report indicated Patient #3</p>			

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	<p>"became loud and argumentative" with the technician and refused to allow the technician to continue working with Patient.</p> <p>During an interview with PCT 1 on 2/14/24 beginning at 12:00 PM, the technician reported he/she had "issues" with Patient #3 prior to the 2/09/24 alleged incident. PCT 1 reported in 2023, Patient became upset when the technician would not put the patient's shoes on. PCT 1 reported Patient #3 filed a complaint regarding the 2023 incident and since then, the technician would limit his/her work with Patient #3 to only managing the patient's dialysis machine.</p> <p>Patient #3's medical record included a Progress Note documented on 3/22/23 by MSW 1. The note indicated PCT 1 reported during treatment, Patient #3 "became verbally abusive because [Patient] disagreed" about his/her dialysis prescription orders. Patient reported he/she did not want PCT 1 to continue to work with him/her. The social worker documented they would "continue to monitor/assist as needed." The record failed to evidence staff conducted any further follow-up regarding the incident.</p> <p>The facility's adverse event log evidenced an event documented on 5/31/23 by RN 1. The event report indicated Patient #3 was "loud and argumentative and yelling with techs." Patient reportedly "continued ranting in waiting room" about RN 1.</p> <p>The facility's adverse event log evidenced an event documented on 6/07/23 by PCT 2. The event report indicated Patient #3 pushed the technician away and would not allow the technician to perform care to Patient's central venous catheter (CVC). The report indicated</p>			

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	<p>Patient was "loud and argumentative."</p> <p>Patient #3's medical record included a Clinical Note documented on 6/13/23 by Administrator. The note indicated Administrator called both Patient #3 and Family Member A to attempt to schedule a meeting with the IDT, however Administrator was unable to reach either Patient or family member. The note failed to evidence the reason for the meeting. The record failed to evidence documentation of any further attempts to conduct a meeting between the IDT and Patient #3.</p> <p>The record included a Progress Note documented on 10/23/23 by MSW 1. The note indicated Clinic Manager 2 reported Patient #3 would "not listen to staff ... regarding [his/her] treatment. [Patient #3] will not adhere to treatment orders. [Patient #3] is calling staff murderers and killers and most staff are afraid to work with [him/her. The clinic manager] is trying to have a meeting" The record failed to evidence when the IDT held or attempted to hold a meeting with Patient #3 regarding his/her reported behaviors.</p> <p>The record included a Progress Note documented on 12/01/23 by MSW 1. The note indicated Clinic Manager 2 reported Patient #3 had "snatched an item" out of RN 3's hands and had been "disruptive." The note indicated the social worker would "continue to monitor/assist as needed." The record failed to evidence the IDT held or attempted to hold a meeting with Patient #3 regarding his/her reported behaviors.</p> <p>During an interview with MSW 1 on 2/15/24 beginning at 11:07 AM, the social worker reported the facility attempted to conduct a meeting with Patient #3 regarding his/her behavior after the</p>			

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	<p>October or December incidents but could not recall when the attempted meeting occurred. MSW 1 reported Clinic Manager 2 was responsible for setting up the meeting, so the social worker did not document these attempts. MSW 1 reported Patient did not attend the meeting. The social worker could not recall any further interventions were performed by the facility regarding Patient's behavior.</p> <p>The record included a Progress Note documented on 2/12/24 by MSW 1. The note indicated a meeting was held with "managers" regarding possible involuntary discharge of Patient #3. MSW 1 documented "per meeting with management, [Corporate Employee 1], clinic will start involuntary discharge."</p> <p>The record included a second Progress Note documented on 2/12/24 by MSW 1. The note indicated the IDT met with Patient #3. During the meeting, Patient #3 was given a notification of involuntary discharge "due to disruptive behaviors and threats to staff" and Patient was given a behavioral agreement.</p> <p>The review of the facility's adverse event log between 2/14/23 - 2/14/24 evidenced 2 adverse events involving Patient #3 dated 02/09/24. The log included:</p> <p>a. An adverse event for "hemolysis" documented by PCT 1 at 9:19 AM. The event report indicated after performing Patient #3's CVC care, the technician secured Patient #3's CVC lines to Patient's left shoulder. Patient began to pull the lines and "direct where [he/she] would like to place the tape." PCT 1 documented he/she asked Patient to loosen the arterial line "to prevent the machine from alarming due to noticing</p>			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152501	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 02/22/2024
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE GARY	STREET ADDRESS, CITY, STATE, ZIP COD 3290 GRANT ST GARY, IN 46408
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	<p>restriction." Patient #3 "became argumentative," telling the technician "that is not the reason for the machine alarming," and asking the technician to "just do what [he/she] was asked to do." PCT 1 documented he/she placed tape where Patient requested and Patient "yelled out ... I know you just didn't hit me! Back away from me!" The event report indicated the technician [sic] "confessed that [he/she] did not hit [Patient #3]," left Patient's station, and informed the facility's management. PCT 1 documented Patient #3 "called the police to make a report."</p> <p>Review of Patient #3's clinical record evidenced Patient's dialysis treatment began on 2/09/24 at 7:04 AM. Review of the police report filed regarding the police investigation of PCT 1's alleged assault against Patient indicated the assault was initially reported to the police at 7:09 AM. The police officer's last radio log was at 8:16 AM to report the investigation was complete. Patient #3's treatment floor sheet indicated the patient's treatment ended at 8:57 AM, which was after Patient and Administrator spoke.</p> <p>b. An adverse event for "Dialysis Weight/ [Ultrafiltration] Goal Variance" documented by Administrator at 3:11 PM. The event report indicated Patient #3 "had a behavioral occurrence while at treatment ... [Patient] had an outburst, called the police alleging that [he/she] was assaulted by a PCT. [Patient #3] threatened stating that [he/she] 'should've fight [sic] [the technician] back.' [Patient #3's] treatment was immediately ended." The event report indicated Patient #3 was discharged.</p> <p>4. The review of the facility's list of unstable patients for November 2023 - February 2024, provided by the Administrator on 2/15/24, failed</p>			

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

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	to evidence Patient #3 was listed as "unstable" for any of these months. 5. The review of the faciliy's Governing Body meeting minutes failed to evidence the Governing Body was overseeing Patient #3's involuntary discharge and ensuring all requirments for involuntary discharge according to the facility's policies were met prior to the facility notifying Patient of a pending involuntary dishcharge.			