STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152542	A. BUILDING 00 B. WING	01/27/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE NEPHROLOGY BLACKTHORN	6201 NIMTZ PKWY SOUTH BEND, IN 46628

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
E 0000 Bldg. 00	An Emergency Preparedness survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62, for a Medicare participating End Stage Renal Disease Supplier. Date of survey: 1/21/2022 to 1/27/2022 Facility #: 009879 CCN: 152542 Stations: 24 ICHD Patients: 91 Total Census: 91 At this Emergency Preparedness survey, Fresenius Medical Center Nephrology- Blackthorn has been found to be in compliance with the requirements of Emergency Preparedness Requirements for Medicare participating providers and suppliers, including staffing and implementation of staffing during a Pandemic, at 42 CFR 494.62.	E 0000		
V 0000 Bldg. 00	This survey was a Federal Re-certification and complaint survey. Complaint #: IN00353279: Complaint was unsubstantiated. Federal deficiencies unrelated to the complaint were cited.	V 0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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	Date of survey: 1/21/2022 to 1/27/2022 Facility #: 009879 CCN: 152542 Stations: 24 ICHD Patients: 91 Total Census: 91 Quality Review Completed 02/02/2022			
V 0113 Bldg. 00	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. Based on observation, record review, and interview, the facility failed to ensure staff had completed appropriate hand hygiene according to hand hygiene policies and procedures in 8 of 10 handwashing observations completed. (PCT L, PCT K, PCT P, PCT M, PCT J, PCT H) The findings include: 1. An agency policy titled "Hand Hygiene," revised 11/4/2019, stated "Purpose: the purpose of this policy is to prevent the transition of pathogenic microorganisms to patients and staff through cross contamination ... Policy: Hand hygiene includes either washing hands with soap and water or using a waterless alcohol-based	V 0113	On February 11, 2022, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy & procedure: · Hand Hygiene Education emphasis was placed on: · Change gloves and practice hand hygiene between each patient and station to prevent cross-contamination. · Removal of soiled gloves and performing hand hygiene after direct contact with patient and/or after contact with inanimate	02/26/2022

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	antiseptic rub with 60-90% alcohol content. Hands will be washed with antimicrobial soap and water when hands are visibly dirty or contaminated with proteinaceous material, blood, or other bodily fluids ... decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water before and after direct contact with patients. Entering and leaving the treatment area. Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications. Immediately after removing gloves. After contact with bodily fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled. When moving from a contaminated body site to a clean body site of the same patient. After contact with the dialysis wall box, concentrate, drain or water lines ...." 2. An agency procedure titled "Hand Hygiene," revised 9/26/2018 stated, "Procedure for Washing Hands with Soap and Water: 1. If gloves are worn remove and discard in appropriate waste container ... 2. Turn on warm running water ... 3. Wet hands with running water. Water is needed to lather soap. 4. Apply soap to hands using the amount recommended by the product manufacturer ... 5. Rub hands together vigorously. Cover all surfaces of the hands and fingers ... Duration of the entire procedure 40-60 seconds. 6. Rinse hands with running water and dry thoroughly with a disposable towel ... Turn of water faucet by using a hands free control or by touching the sink with wrist blades with a clean single use paper towel ... Procedure for Decontaminating Hands with Alcohol Based Hand rubs 1. If gloves are worn, remove and discard in appropriate waste container. Exposes the skin for decontamination. 2. Apply alcohol-based hand rub to the palm of one hand		objects within the hemodialysis station such as supply drawers, stethoscope, etc. · Hand hygiene may be performed by hand washing or using an alcohol based hand rub. · Hand washing will include wetting hands, applying soap, rubbing hands vigorously, rinsing hands under running water and drying thoroughly with a disposable towel. Duration of the entire hand washing procedure will be 40-60 seconds. · Decontaminating hands with an alcohol based hand rub includes applying hand rub, rub hands together covering all surfaces of hands and fingers, allow to dry. Duration of the entire hand rub decontaminating procedure will be 20 seconds. Effective February 14, 2022, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on changing gloves and practicing hand hygiene per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month	

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	using the amount recommended by the product manufacturer. Adequate amount of product must be used for maximum effectiveness. 3. Rub hands together covering all surfaces of the hands and fingers until hands are dry. Allowing alcohol to dry completely allows adequate contact time to kill germs, allows alcohol to evaporate, and prevents risk of igniting flames due to alcohol's flammable properties. Duration of the entire procedure: 20 to 30 seconds...." 3. During an observation on 1/21/2022 at 1:01 PM, PCT (Patient Care Technician) L was observed accessing patient #9's fistula (an abnormal connection between an artery and a vein) PCT L was observed sanitizing her hands with an alcohol-based hand rub. PCT L waved her hands to try and dry the hand sanitizer. PCT L failed to rub all surfaces of her hands until the alcohol-based hand rub was dry. 4. During an observation on 1/21/2022 at 12:00 PM, PCT K was observed discontinuing dialysis for patient #11, at station #6. PCT K disconnected the bloodlines from patient #11 and went to the sink to wash her hands. PCT K washed her hands with soap and water for 10 seconds. PCT K failed to wash her hands for a minimum of 20 seconds. 5. During an observation on 1/21/2022 at 12:30 PM, PCT L was observed discontinuing dialysis for patient #12, at station #24. PCT L disconnected the bloodlines from patient #12. PCT L was observed sanitizing her hands with an alcohol-based hand rub. PCT L waved her hands to dry the hand sanitizer. PCT L failed to rub all surfaces of her hands until the alcohol-based hand rub was dry. 6. During an observation on 1/21/2022 at 12:23		at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: February 26, 2022	

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	PM, PCT L was observed doing exit site care on patient #8, at station #4. PCT L cleansed the site and applied a new dressing and proceeded to put a clean field under the catheter ports. PCT L failed to wash or sanitize her hands after cleaning the site and applying the new dressing to the exit site. 7. During an observation on 1/21/2022 at 11:22 AM, PCT M was observed drawing up heparin into a syringe. PCT M gave the syringe to PCT N, donned a pair of gloves, and went to station #10 to set up the machine. PCT M failed to wash or sanitize her hands prior to donning her gloves. 8. During an observation on 1/21/2022 at 2:21 PM, PCT P was observed drawing up heparin into a syringe. PCT P took the syringe to station #13, for patient #11. PCT P donned a pair of gloves failing to be observed to have washed or sanitized her hands prior to donning her gloves. PCT P then went to station #8 and was typing on the computer. 9. During an observation on 1/27/2022 at 11:10 AM, PCT J was observed setting up the machine at station #9. PCT J donned a pair of gloves and primed dialyzer at station #9. PCT J failed to wash or sanitize her hands prior to donning her gloves. 10. During an observation on 1/27/2022 at 10:47 AM, PCT H was on observed obtaining supplies to set up the machine at station #3. PCT H put the tubing, dialyzer, and saline on the chair. PCT H donned gloves failing to wash her hands prior to donning the gloves and proceeded to set up the machine. During an interview on 1/27/2022 at 3:08 PM, the clinical manager indicated hand washing should take a total of 40-60 seconds, with 20 seconds to			

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	rub all surfaces of the hands with soap. She indicated when using an alcohol-based hand rub the procedure takes about 20-30 seconds and the hands should be fully dry when completed..			
V 0122 Bldg. 00	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, record review and interview, the facility failed to ensure staff had completed appropriate disinfection of dialysis stations in 2 of 2 disinfection of stations observed. (Station #5, #10) The findings include: 1. An agency policy titled "Cleaning and Disinfection of the Dialysis Station," revised 11/2/2020 stated, "Purpose: The purpose of this policy is to provide guidelines to prevent the spread of infectious disease in accordance with appropriate regulations, and to maintain, a clean, safe aesthetically pleasant environment for patients, staff, in visitors ... Definition: Dialysis station Area including the dialysis machine, chair/bed and other reusable equipment utilized during the dialysis treatment. Equipment in the dialysis station may include but is not limited to) the following: Dialysis machine and attachments such as IV [intravenous] pole, BP [blood	V 0122	On February 11, 2022, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Cleaning and Disinfection of the Dialysis Station Education emphasis was placed on: · Cleaning and disinfected all work surfaces within the hemodialysis station with 1:100 bleach solution after completion of procedures; including but not limited to the back of machine, IV poles, and shelf behind the hemodialysis station. · Ensure the surfaces are glistening wet and allow to air dry before placing the next patient into the hemodialysis station. Effective February 14, 2022, the	02/26/2022

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	pressure] cuff and hand sanitizer/holder, chair, individual television and remote ... the dialysis station could become contaminated with blood or other body fluids during treatment. After use, all non- disposable equipment and supplies must be disinfected with 1:100 bleach or manufacturer's recommendations or discarded ... Externally disinfect the dialysis machine with 1:100 bleach solution after each dialysis treatment...." 2. An agency procedure titled "Cleaning and Disinfection of the Dialysis Station " revised 3/20/2013 stated, " ... 3. Use a cloth wetted with 1:100 bleach solution or EPA-approved disinfectant to clean and disinfect the dialysis station (chair/bed, tables, machine, television, IV pole, BP cuff, hand sanitizer dispenser, and holder etc.). Place the chair in Trendelenburg position and open side panels if chair has swing open sides do all the surfaces are visible 4. Clean all surfaces, Make sure the surfaces are glistening wet and allow to air dry ... 5. Give special attention to the cleaning of the control panel on the dialysis machine and other surfaces that are frequently touched and potentially contaminated with the patient's blood and/or bodily fluids. While wiping, remember, 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...." 3. During an observation on 1/21/2022 at 12:15 PM, PCT (patient care technician) H was observed cleaning station #5. PCT H failed to clean the back of the machine, the IV (intravenous) pole, and the shelf behind the station 4. During an observation on 1/21/2022 at 2:50 PM, PCT J was observed cleaning machine 234140 at		Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be cleaning all work surfaces within the hemodialysis station with 1:100 bleach solution per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to	

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	station #10. PCT J failed to clean the back of the machine and the shelf behind the machine during the cleaning process. During an interview on 1/24/2022 at 3:15 PM, the clinical manager indicated everything at the station needs to be cleaned after patient use, including the back of the machine, the shelf behind the chair, and the IV poles.		address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: February 26, 2022	
V 0143 Bldg. 00	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 Based on observation, record review, and interview, the dialysis facility failed to ensure the staff wiped the stopper of a multi-dose medication vial with an alcohol wipe for 1 of 2 observations of medication administration. (PCT O) The findings include: An agency policy titled "Medication Preparation and Administration Procedure, " published 11/2/2020, stated " ... Select the appropriate size syringe. Remove the protective cap from vial and wipe the rubber stopper with alcohol prep pad. Do not touch stopper after cleaning, Use a new alcohol prep pad for each vial...." During an observation of a parenteral medication preparation and administration on 1/26/2022 at 10:47 AM, PCT (patient care technician) O, was	V 0143	On February 11, 2022, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Medication Preparation and Administration Education emphasis was placed on: · Ensure staff wipe the rubber stopper of a multi-dose medication vial with an alcohol wipe prior to insertion of a needle, including but not limited to heparin multi-dose vials. Effective February 14, 2022, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one	02/26/2022

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	observed to draw up Heparin (used to prevent blood clots) from a multi-dose vial by inserting a sterile needle into the stopper of the vial and withdrawing the heparin medication into the syringe. PCT O failed to wipe the opened heparin vial with an alcohol pad prior to inserting the syringe needle into the vial. PCT O was then observed to take the syringes to station # 9 for patient # 10. During an interview on 1/27/2022 at 2:01 PM, the clinical manager indicated the rubber stopper of the vial should be cleaned with alcohol before inserting the needle.		month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on utilization of an alcohol swab on per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing	

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			Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: February 26, 2022	
V 0504 Bldg. 00	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. Based on record review and interview, the dialysis facility failed to ensure patient pre/post and intradialytic blood pressures were being assessed and managed in 6 of 7 in-center hemodialysis records reviewed. (Patient #1, #2, #3, #4, #5, #7) 1. An agency document titled "Hypertension" published 9/7/2021, stated, "Staff will recognize, report, and immediately address systolic blood pressures greater than 180 mm/Hg [millimeters of mercury] and/or diastolic blood pressures greater than 100 mm/Hg ... Treating Hypertension: ... If hypertension is not related to hypervolemia notify the physician for additional orders/interventions...." 2. An agency document titled "Hypotension" published 9/7/2021, stated, " ... Staff, patient and/or care partner will report hypotensive episodes to the nurse in charge The nurse in charge will report to the physician severe or frequent hypotensive episodes...." 3. Record review on 1/25/2022 for patient #1, start of care 7/25/2019, evidenced an agency document	V 0504	On February 11, 2022, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Patient Assessment and Monitoring · Hypertension · Intradialytic Hypotension Education emphasis was placed on: · Patient Care Technicians (PCTs) are required to notify the Registered Nurse (RN) for SBP >180 mm/Hg or <100 mm/Hg and/or DBP >100 mm/Hg or <50 mm/Hg. · Staff will recognize, report, and immediately address systolic blood pressures greater than 180 mm/Hg [millimeters of mercury] and/or diastolic blood pressures greater than 100 mm/Hg; if hypertension is not related to hypervolemia notify the physician	02/26/2022

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	titled "Treatment Sheet for Facility" dated 1/4/2022. This document indicated the patient's blood pressure at the beginning of treatment was 136/90 (normal blood pressure is 120/80), during treatment at 8:02 AM, patient #1's blood pressure was 149/102. This document failed to evidence the PCT (Patient Care Technician) K notified the nurse of the patient's high diastolic blood pressure. Record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/6/2022. This document indicated the patient's blood pressure at the beginning of treatment was 142/89, during treatment at 8:04 AM, patient #1's blood pressure was 157/103, at 8:35 AM, patient #1's blood pressure was 162/100. This document failed to evidence the physician was notified of the patient's high diastolic blood pressure. 4. Record review on 1/25/2022 for patient #2, start of care 4/13/2020, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/20/2022. This document indicated the patient's blood pressure at the beginning of treatment was 160/92, during treatment at 8:33 AM, patient #2's blood pressure was 159/102, at 9:01 AM, patient #2's blood pressure was 174/108, at 10:01 AM, the patient's blood pressure was 192/110, and at 11:32 AM, patient #2's blood pressure as 186/107. This document failed to evidence the physician and the nurse were notified of the patient's high diastolic blood pressure. 5. Record review on 1/25/2022 for patient #3, start of care 2/24/2014, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/14/2022. This document indicated the patient's blood pressure at the beginning of treatment was		for additional orders/interventions. · Staff, patient and/or care partner will report hypotensive episodes to the nurse in charge; the nurse in charge will report to the physician severe or frequent hypotensive episodes. · The RN will document in the electronic medical record any blood pressures out of parameters, with an assessment and intervention when indicated. Effective February 14, 2022, the Clinical Manager or designee will conduct hemodialysis treatment sheet audits on a minimum of ten patient records daily, rotating shifts, for two weeks, then weekly for four weeks, then every two weeks for one month utilizing the Patient Treatment Sheet Monitoring Tool. The focus will be on documentation of RN notification, assessment and intervention, including physician notification, when indicated for BP out of parameters per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and	

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	152542	A. BUILDING 00 B. WING	01/27/2022

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FRESENIUS MEDICAL CARE NEPHROLOGY BLACKTHORN	6201 NIMTZ PKWY SOUTH BEND, IN 46628

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
	121/60, during treatment at 2:01 PM, patient #3's blood pressure was 136/115. This document failed to evidence the physician and the nurse were notified of the patient's high diastolic blood pressure. Record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 12/31/2021. This document indicated the patient's blood pressure at the beginning of treatment was 137/69, during treatment at 12:07 PM, patient #3's blood pressure was 89/47, at 1:11 PM, patient #3's blood pressure was 96/50. This document failed to evidence the physician and nurse were notified of the patient's low blood pressure. 6. Record review on 1/25/2022 for patient #4, start of care 9/11/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/5/2022. This document indicated the patient's blood pressure at the beginning of treatment was 112/81, during treatment at 8:30 AM, patient #4's blood pressure was 97/65, and at 9:36 AM, patient #4's blood pressure was 97/57. This document failed to evidence the physician and nurse were notified of the patient's low blood pressure. 7. Record review on 1/25/2022 for patient #5, start of care 11/21/2018, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/10/2022. This document indicated the patient's blood pressure at the beginning of treatment was 124/70, during treatment at 12:32 PM, patient #5's blood pressure was 193/124, at 1:39 PM, patient #5's blood pressure was 218/124, and at 3:03 PM, the patient's blood pressure was 212/105. This document failed to evidence the physician and nurse were notified of the patient's		trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: February 26, 2022	

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	high blood pressure. Record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/12/2022. This document indicated the patient's blood pressure at the beginning of treatment was 197/120, during treatment at 12:34 PM, patient #5's blood pressure was 205/127, at 1:32 PM, patient #5's blood pressure was 187/105, and at 3:00 PM, the patient's blood pressure was 185/104. This document failed to evidence the physician and nurse were notified of the patient's high blood pressure. Record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/14/2022. This document indicated the patient's blood pressure at the beginning of treatment was 154/92, during treatment at 12:41 PM, patient #5's blood pressure was 175/106, at 1:39 PM, patient #5's blood pressure was 218/124, and at 3:02 PM, the patient's blood pressure was 277/101. This document failed to evidence the physician and nurse were notified of the patient's high blood pressure. Record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/17/2022. This document indicated the patient's blood pressure at the beginning of treatment was 193/115, during treatment at 3:04 PM, patient #5's blood pressure was 213/118, and at 3:32 PM, patient #5's blood pressure was 193/112. This document failed to evidence the physician and nurse were notified of the patient's high blood pressure. Record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/21/2022. This document indicated the			

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	patient's blood pressure at the beginning of treatment was 202/105, during treatment at 1:08 PM, patient #5's blood pressure was 176/108, at 1:39 PM, patient #5's blood pressure was 197/113, and at 3:30 PM, the patient's blood pressure was 188/108. This document failed to evidence the physician and nurse were notified of the patient's high blood pressure. 8. Record review on 1/25/2022 for patient #7, start of care 11/12/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/210/2022. This document indicated the patient's blood pressure at the beginning of treatment was 112/60, during treatment at 9:05 PM, patient #7's blood pressure was 136/103. This document failed to evidence the physician and nurse were notified of the patient's high blood pressure. During an interview on 1/27/2022 at 3:42 PM, the clinical manager indicated when the patient's blood pressure is high or low compared to their normal parameters the PCT should alert the nurse. She indicated the nurse would assess the patient to determine if a call to the physician was needed.			
V 0543 Bldg. 00	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; Based on record review, and interview, the facility failed to ensure the physician was aware of the inability of the patient to achieve their dry weight to establish the appropriateness of the dialysis prescriptions in 3 of 7 in-center hemodialysis	V 0543	On February 11, 2022, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on the following policy:	02/26/2022

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	patient's clinical records reviewed (patient #1, #2, #6), and failed to ensure patients blood pressures were monitored per policy in 7 of 7 in-center hemodialysis patient's clinical records reviewed. (patient #1, #2, #3 #4, #5, #6, #7) The findings include: 1. An agency policy titled "Volume Management in ESRD [End Stage Renal Disease] Patients on Hemodialysis" published 9/7/2021, stated "If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with the physician for appropriate fluid interventions: Pre-treatment hypervolemia Pre-treatment sitting systolic BP is greater than 160 mmHg and prior treatment post dialysis sitting systolic BP is greater then 140 mmHg Pre-treatment signs or symptoms of hypervolemia: ... Pre-treatment weight is less than or equal to EDW .... EDW order should be updated post 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...." 2. An agency policy titled "Patient Assessment and Monitoring" published 9/29/2018, stated, "If the PCT/LPN [patient care technician/licensed practical nurse] note any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or if the patient was hospitalized, the patient care technician MUST report the changes to a registered nurse Any abnormal finding confirmed by the RN [registered nurse] will be reported to the attending physician ... Maintain the patient post treatment weight and ensure the post weight is consistent with the goal set of the machine ... Obtain blood pressure and pulse rate every 30		· Volume Management in ESRD [End Stage Renal Disease] Patients on Hemodialysis · Patient Assessment and Monitoring Education emphasis was placed on: · Ensure the physician is aware of the inability of the patient to achieve their estimated dry weight (EDW) to establish the appropriateness of the dialysis prescriptions. · Ensure patient's blood pressures are monitored per policy. · Ensuring vital signs and treatment status of the patient are monitored every 30 minutes or more frequently if indicated. Effective February 14, 2022, the Clinic Manager or designee will conduct hemodialysis treatment sheet audits on a minimum of ten patient records daily, rotating shifts, for two weeks, then weekly for four weeks, then every two weeks for one month utilizing the Patient Treatment Sheet Monitoring Tool. The focus will be notifying the physician if EDW is not achieved and completing 30 minute vital signs per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.	

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	minutes or more as needed but not to exceed 45 minutes per state regulations...." 3. Clinical record review on 1/25/2022, for patient #1, start of care 7/25/2019, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/8/2022. This document indicated patient #1's dry weight [a weight without excess fluid] was 67 kilograms (kg). At the completion of treatment patient #1's weight was 68 kg. This document failed to evidence the physician was informed patient #1 failed to achieve his target dry weight. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/11/2022. This document indicated patient #1's dry weight was 67 kilograms. At the completion of treatment patient #1's weight was 69.5 kg. This document failed to evidence the physician was informed patient #1 failed to achieve his target dry weight. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/11/2022. This document indicated patient #1's blood pressure was monitored at 9:06 AM, the next blood pressure monitored for patient #1 was at 10:04 AM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/13/2022. This document indicated patient #1's dry weight was 67 kilograms. At the completion of treatment patient #1's weight was 71.2 kg. This document failed to evidence the physician was informed patient #1		The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: February 26, 2022	

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	failed to achieve his target dry weight. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/15/2022. This document indicated patient #1's dry weight was 67 kilograms. At the completion of treatment patient #1's weight was 68.9 kg. This document failed to evidence the physician was informed patient #1 failed to achieve his target dry weight. During an interview on 1/26/2022 at 3:02 PM, the clinical manager indicated patient #1's dry weight should have been monitored and adjusted. 4. Clinical record review on 1/25/2022, for patient #2, start of care 4/13/2020, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/4/2022. This document indicated patient #2's blood pressure was monitored at 10:16 AM, the next blood pressure monitored for patient #2 was at 11:14 AM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/20/2022. This document indicated patient #2's blood pressure was monitored at 10:01 AM, the next blood pressure monitored for patient #2 was at 11:32 AM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. 5. Clinical record review on 1/25/2022, for patient #3, start of care 2/24/2014, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/17/2022. This document indicated patient #3's blood pressure was monitored at 3:07 PM, the			

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	next blood pressure monitored for patient #3 was at 4:02 PM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/21/2022. This document indicated patient #3's blood pressure was monitored at 3:00 PM, the next blood pressure monitored for patient #3 was at 4:13 PM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. 6. Clinical record review on 1/25/2022, for patient #4, start of care 9/11/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/3/2022. This document indicated patient #4's blood pressure was monitored at 7:07 AM, the next blood pressure monitored for patient #4 was at 8:12 AM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/5/2022. This document indicated patient #4's blood pressure was monitored at 9:36 AM, the next blood pressure monitored for patient #4 was at 10:46 AM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/10/2022. This document indicated patient #4's blood pressure was monitored at 6:59 AM, the next blood pressure monitored for patient #4 was at 8:04 AM. This			

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	document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/14/2022. This document indicated patient #4's blood pressure was monitored at 6:55 AM, the next blood pressure monitored for patient #4 was at 8:02 AM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/19/2022. This document indicated patient #4's blood pressure was monitored at 10:03 AM, the next blood pressure monitored for patient #4 was at 11:03 AM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. 7. Clinical record review on 1/25/2022, for patient #5, start of care 11/21/2018, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/14/2022. This document indicated patient #5's blood pressure was monitored at 12:41 PM, the next blood pressure monitored for patient #5 was at 2:02 PM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/21/2022. This document indicated patient #5's blood pressure was monitored at 1:30 PM, the next blood pressure monitored for patient #5 was at 2:33 PM. This			

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	document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. 8. Clinical record review on 1/25/2022, for patient #6, start of care 9/24/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/14/2022. This document indicated patient #6's dry weight was 94 kilograms. At the completion of treatment patient #6's weight was 91.8 kg. This document failed to evidence the physician was informed patient #6 failed to achieve her target dry weight. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/17/2022. This document indicated patient #6's dry weight was 94 kilograms. At the completion of treatment patient #6's weight was 92 kg. This document failed to evidence the physician was informed patient #6 failed to achieve her target dry weight. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/19/2022. This document indicated patient #6's dry weight was 94 kilograms. At the completion of treatment patient #6's weight was 91.8 kg. This document failed to evidence the physician was informed patient #6 failed to achieve her target dry weight. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/3/2022. This document indicated patient #6's blood pressure was monitored at 2:02 PM, the next blood pressure monitored for patient #6 was at 3:08 PM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy.			

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	Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/5/2022. This document indicated patient #6's blood pressure was monitored at 12:25 PM, the next blood pressure monitored for patient #6 was at 1:42 PM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/7/2022. This document indicated patient #6's blood pressure was monitored at 12:00 PM, the next blood pressure monitored for patient #6 was at 12:51 PM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/12/2022. This document indicated patient #6's blood pressure was monitored at 2:02 PM, the next blood pressure monitored for patient #6 was at 3:04 PM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/17/2022. This document indicated patient #6's blood pressure was monitored at 11:54 AM, the next blood pressure monitored for patient #6 was at 1:03 PM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. Clinical record review on 1/25/2022, evidenced an			

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	agency document titled "Treatment Sheet for Facility" dated 1/19/2022. This document indicated patient #6's blood pressure was monitored at 2:02 PM, the next blood pressure monitored for patient #6 was at 3:07 PM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. 9. Clinical record review on 1/25/2022, for patient #7, start of care 11/12/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/7/2022. This document indicated patient #7's blood pressure was monitored at 6:35 PM, the next blood pressure monitored for patient #7 was at 7:34 PM. This document failed to evidence the patient's blood pressure was monitored every 30 minutes per facility policy. During an interview on 1/27/2022 at 3:08 PM, the clinical manager indicated the staff should be monitoring patients every 30 minutes, including their blood pressure. She indicated there should be a line on the treatment sheet with the blood pressure recorded and acknowledged by staff every 30 minutes.			
V 0544 Bldg. 00	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. Based on record review and interview, the facility failed to ensure patient dialysis prescription orders were verified and adhered to in order to achieve and sustain the prescribed dose of	V 0544	On February 11, 2022, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy & procedure:	02/26/2022

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	dialysis to meet the adequacy of dialysis in 5 out of 7 in-center hemodialysis clinical records reviewed. (#1, #2, #3, #4, #5) The findings include: 1. An agency policy titled "Patient Assessment and Monitoring, " published 9/29/2018, stated " ... 3. Check the machine settings and measurements, check the prescribed blood flow rate is being achieved or reason in the medical record if unable to meet the prescribed flow rate. Check dialysate flow rate setting is correct the prescribed flow is being delivered...." 2. Clinical record review on 1/25/2022 for patient #1, start of care 7/25/2019, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/6/2022. This document indicated the patient's prescribed BFR (blood flow rate)was 500 ml/min (milliliters/minute). During this treatment patient #1's BFR was 300 ml/min. This document failed to indicate documentation as to why patient #1 did not get her prescribed treatment. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/15/2022. This document indicated the patient's prescribed BFR was 500 ml/min. During this treatment patient #1's BFR was 200 ml/min for the first hour of treatment. This document failed to indicate documentation as to why patient #1 did not get her prescribed treatment. 3. Clinical record review on 1/25/2022 for patient #2, start of care 4/13/2020, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/22/2022. This document indicated patient #2's prescribed BFR was 600 ml/min. During this		· Patient Assessment and Monitoring Emphasis was placed on: · Ensure patient dialysis prescription orders were verified and adhered to in order to achieve and sustain the prescribed dose of dialysis to meet the adequacy of dialysis. · The registered nurse must evaluate each patient, review patient treatment prescription to verify setting and if dialysis prescription is being followed. · Verifying machine settings and measurements to match the dialysis prescription. · Verifying prescribed blood flow rate (BFR) is being achieved or reason is documented in medical record if unable to meet the dialysis prescription. Effective February 14, 2022, the Clinical Manager or designee will conduct hemodialysis treatment sheet audits on a minimum of ten patient records daily, rotating shifts, for two weeks, then weekly for four weeks, then every two weeks for one month utilizing the Patient Treatment Sheet Monitoring Tool. The focus will be on documentation of BFR achieved as prescribed or MD notification when indicated. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI)	

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	152542	A. BUILDING 00 B. WING	01/27/2022

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	treatment patient #2's BFR was 550 ml/min. This document failed to evidence documentation as to why patient #2 did not get his prescribed treatment. 4. Clinical record review on 1/25/2022 for patient #3, start of care 2/24/2014, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/12/2022. This document indicated patient #3's prescribed BFR was 450 ml/min. During this treatment patient #3's BFR was 500 ml/min. This document failed to evidence documentation as to why patient #3 did not get his prescribed treatment. 5. Clinical record review on 1/25/2022 for patient #4, start of care 9/11/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/5/2022. This document indicated patient #4's prescribed BFR was 450 ml/min. During this treatment patient #4's BFR was 400 ml/min. This document failed to evidence documentation as to why patient #4 did not get her prescribed treatment. Clinical record review on 1/25/2022 for patient #4, start of care 9/11/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/17/2022. This document evidenced patient #4's prescribed BFR was 450 ml/min. During this treatment patient #4's BFR was 400 ml/min. This document failed to evidence documentation as to why patient #4 did not get her prescribed treatment. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/19/2022. This document indicated patient #4's prescribed BFR was 450 ml/min. During this treatment patient #4's BFR was		calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manger is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues. The in-service sheets are available in the clinic for review. Completion Date: February 26, 2022	

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	dropped to 400 ml/min. This document failed to evidence documentation as to why patient #4 did not get her prescribed treatment. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/21/2022. This document indicated patient #4's prescribed BFR was 450 ml/min. During this treatment patient #4's BFR was 430 ml/min. This document failed to evidence documentation as to why patient #4 did not get her prescribed treatment. 6. Clinical record review on 1/25/2022 for patient #5, start of care 11/21/2018, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/3/2022. This document evidenced patient #5's prescribed BFR was 450 ml/min. During this treatment patient #5's BFR was 420 ml/min. This document failed to evidence documentation as to why patient #5 did not get her prescribed treatment. Clinical record review on 1/25/2022 for patient #5, start of care 11/21/2018, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/5/2022. This document indicated patient #5's prescribed BFR was 450 ml/min. During this treatment patient #5's BFR was 500 ml/min. This document failed to evidence documentation as to why patient #5 did not get her prescribed treatment. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/7/2022. This document indicated patient #5's prescribed BFR was 450 ml/min. During this treatment patient #5's BFR was 400 ml/min. This document failed to evidence documentation as to why patient #5 did not get			

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	her prescribed treatment. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/14/2022. This document indicated patient #5's prescribed BFR was 450 ml/min. During this treatment patient #5's BFR was 405 ml/min. This document failed to evidence documentation as to why patient #5 did not get her prescribed treatment. Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/21/2022. This document indicated patient #5's prescribed BFR was 450 ml/min. During this treatment patient #5's BFR was 400 ml/min. This document failed to evidence documentation as to why patient #5 did not get her prescribed treatment. 7. Clinical record review on 1/25/2022 for patient #6, start of care 9/24/2021, evidenced agency documents titled "Treatment Sheet for Facility" dated 12/31/2021 and 1/3/2022. These documents indicated patient #6's prescribed BFR was 500 ml/min. During this treatment patient #6's BFR was 300 ml/min. These documents failed to evidence documentation as to why patient #6 did not get her prescribed treatment. Clinical record review on 1/25/2022, evidenced agency documents titled "Treatment Sheet for Facility" dated 1/5/2022, 1/12/2022, 1/14/2022, 1/17/2022, 1/19/2022, and 1/21/2022. These documents indicated patient #6's prescribed BFR was 500 ml/min. During this treatment patient #6's BFR was 400 ml/min. These documents failed to evidence documentation as to why patient #6 did not get her prescribed treatment.			

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	Clinical record review on 1/25/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 1/7/2022. This document indicated patient #6's prescribed BFR was 500 ml/min. During this treatment patient #6's BFR was 350 ml/min. This document failed to evidence documentation as to why patient #6 did not get her prescribed treatment. During an interview on 1/27/2022 at 4:03 PM, the clinical manager indicated occasionally a patient will have to run slower than prescribed due to high pressure. She indicated this should be documented on the treatment sheet. The clinical manager indicated the staff should be following the treatment prescription.			