STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152634	A. BUILDING 00 B. WING	06/06/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNCIE	4021 W KILGORE AVE MUNCIE, IN 47304

(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
V 0000 Bldg. 00	This visit was for a Federal complaint survey of an ESRD Provider. Survey dates: June 5 and 6, 2023 Complaint #IN00409457 was investigated; unrelated deficiencies were cited. Census by Service Type: In Center Hemodialysis: 75 Home Hemodialysis: 3 Home Peritoneal Dialysis: 13 Total Census: 91 Isolation Room: 1 QR: Area 2 on 6/15/23	V 0000		
V 0111 Bldg. 00	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. Based on observations and interview, the dialysis facility failed to ensure staff followed facility policies and procedures specific to fistula and graft access for 2 of 2 observations of staff performed cannulation of a fistula or graft. (Registered Nurse (RN) 1).	V 0111	**V 111 IC-SANITARY ENVIRONMENT** On 6/23/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure:	07/06/2023

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Elizabeth (Betsey)Farrar-McIntyre	Area Team Lead	06/30/2023

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determin other safegaurds 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 disclo 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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	Findings include: 1. During an observation on 6/05/23 observed the following: At 9:54 AM, observed RN 1 cannulate Patient #14; RN 1 failed to clean Patient #14's access sites for at least 30 seconds prior to cannulation. At 10:24 AM, observed RN 1 cannulate Patient #13; RN 1 failed to clean Patient 13's access sites for at least 30 seconds prior to cannulation. 2. During an interview on 6/05/23 at 12:44 PM, Corporate Person 1 confirmed staff should have scrubbed access sites for 30 to 45 seconds before cannulation. 3. Review of Policy "Access Assessment and Cannulation" dated 07/05/22, indicated cannulation sites should be disinfected for a minimum of 30 seconds using 70% alcohol pad, povidone iodine pad, or 2% chlorhexidine and 70% alcohol.		· Access Assessment and Cannulation Emphasis was placed on: · Cannulation sites should be disinfected for a minimum of 30 seconds using 70% alcohol pad, povidone iodine pad, or 2% chlorhexidine and 70% alcohol. Effective 6/26/2023, the Clinical Manager or designee will conduct weekly audits with focus on ensuring all patients access are disinfected per policy for four weeks or until 100% compliance is achieved utilizing the Clinical Practice Checklist Audit Tool. 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 Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution	

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			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 07/06/2023	
V 0112 Bldg. 00	494.30(a) IC-CDC MMWR 2001 The facility must demonstrate that it follows standard infection control precautions by implementing- (1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS			

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	Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009. Based on observation and interview, the dialysis facility failed to ensure staff followed policies and procedures related to infection control for 2 of 3 in-center hemodialysis registered nurses observed (RN 1 and RN 2). Findings include: 1. During an observation on 6/05/23 from 9:22 AM to 10:59 AM observed RN 1 and RN 2 during the provision of care. A. RN 1 failed to ensure their face mask covered their nose while on the treatment floor for the duration of the observation period and failed to ensure their face shield was in place, to shield against possible blood or fluid spatter to the eyes, nose, and mouth while providing CVC site care for Patient #15 and while discontinuing CVC dialysis for Patient #4.	V 0112	**V 112 IC-CDC** On 6/23/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: · Guidance on Dialyzing and Infection Control Practices of COVID-19 in Fresenius Kidney Care (FKC) Dialysis Clinics · Personal Protective Equipment Emphasis was placed on: · **All** FKC Staff, physicians and physician extenders are required to surgical face masks or wear N95 respirator during all patient facing activities. o Gowns, gloves, and face shields/goggles are required based upon the patient care	07/06/2023

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	B. RN 2 failed to ensure their face shield was worn over their face during their provision of direct patient care throughout the observation period. 2. During an interview on 6/05/23 at 12:44 PM, the Corporate Person 1 indicated staff were to wear face masks that cover the face and nose and face shields should be worn when staff have the potential to come into contact with blood. During an interview on 6/06/23 at 4:40 PM, the Corporate Person 2 indicated that face shields should be worn anytime there is a risk of blood splatter, during catheter care, during patient site access and while cleaning machines. 3. Review of Policy "Guidance on Dialyzing and Infection Control Practices of COVID-19 in FKC Dialysis Clinics", dated 5/19/23, indicated that all FKC staff are required to wear surgical face masks or wear N95 respirator during all patient facing activities. 4. Review of Policy "Personal Protective Equipment", dated 2/14/18 indicated that full face shield should be worn in an area at risk for blood splatter or spill. 5. During a flash tour observation on 06/05/23 from 09:22 AM to 10:59 AM, observed Patients #3, #7, #17, #18, and #19 were not wearing a face mask and there was no available face mask visible in the station. At 10:15 AM, observed Patient #18 not wearing a mask while being taken off the dialysis machine. 6. Review of policy 64147 "Guidance on Dialyzing		activity being performed. o Staff should adhere to Personal Protective Equipment: § face masks should cover the nose and mouth. § Face shields should be worn down over eyes, face, and nose during patient care. · FKC patients and visitors are required to wear surgical face masks upon entry to the dialysis clinic and throughout the duration of dialysis treatment and discharge from the clinic post-treatment. o Patients will not be refused treatment if a mask is not worn during the non-contact portion of treatment. At a minimum, FKC patients are **required** to wear surgical face masks or N95 mask while in the lobby and when interacting with staff during patient care activities (e.g., cannulation, initiation and termination of treatment, medication administration, central venous catheter care, home therapy clinic visits, etc.). o Staff should ensure that the patient's face mask is properly positioned over the nose and mouth before approaching the patient. Effective 6/26/2023, the Clinical Manager or designee will conduct weekly audits with focus ensuring staff and patients wear face masks covering nose and mouth, as well as, staff have a face shield	

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	and Infection Control Practices of COVID-19 in Fresenius Kidney Care (FKC) Dialysis Clinics," revised 05/19/23, indicated patients should have worn face masks upon entry to the facility, throughout treatment, and throughout discharge from the facility and indicated at minimum patients were required to wear a mask when interacting with staff during patient care activities which included but not limited to initiation and discontinuation of treatment. The policy also indicated staff should have ensured patients were wearing a mask properly positioned over the nose and mouth before approaching the patient. 7. During an interview on 06/05/23 at 12:44 PM, Corporate Person 1 indicated patients were required to wear a mask when in contact with staff and indicated they could pull it down on the chin when alone in the station but should have pulled it back up over the nose and mouth when approached by staff.		in place covering eyes, nose and mouth during possible blood or fluid spatter events. Per facility policy by staff utilizing Infection Control Audit Tool for four weeks or until 100% compliance is achieved. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the 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	

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			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 07/06/2023	
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 and interview, the dialysis facility failed to ensure staff followed their policies and procedures related to hand hygiene for 1 of 1 Patient Care Technicians (PCT) observed (PCT 1) and 2 of 3 Registered Nurses (RN) observed (RN 1 and 2). Findings include: 1. During an observation on 6/05/23 at 9:51 AM, RN 2 was observed in Station #22 with Patient #14. RN 2 cleaned Patient #14's fistula area, then walked from Station #22 to a supply cabinet, obtained a tourniquet, then returned to Station #22 and resumed accessing Patient #14's fistula. RN 2 failed to complete hand hygiene throughout this observation, wore the same gloves throughout and failed to ensure his / her face shield was in place.	V 0113	**V 113 IC-Wear Gloves/Hand Hygiene** On 6/23/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: · Hand Hygiene Policy and Procedure · Personal Protective Equipment Emphasis was placed on: · Staff should change gloves and practice hand hygiene between each patient and/or station to prevent cross-contamination. · Hands will be: o Decontaminated using alcohol-based hand rub or by washing hands with antimicrobial	07/06/2023

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	2. During an observation on 6/05/23 at 10:24 AM, RN 1 was observed in Station #15 with Patient #13. RN 1 exited Station #15, walked to the supply cabinet, obtained a medication, a vial of Heparin, and drew up heparin into a syringe. RN 1 then adjusted his/her face mask which was below his/her nose as he/she walked back to Station #15; RN 1 then administered Heparin to Patient #13. RN 1 failed to complete hand hygiene throughout this observation, wore the same gloves throughout and failed to ensure his / her face shield was in place. RN 1 then left Station #15, walked to Station #23, reset the monitor and walked back to Station #15. RN 1 failed to remove gloves and perform hand hygiene before caring for another patient and entering their hemodialysis station. 3. During an observation on 6/05/23 at 10:35 AM, observed RN 1 leave Station #16, walked to Station #24 and applied the blood pressure cuff to Patient #7, who was receiving their hemodialysis treatment. RN 1 then walked back to Station #16 and resumed care to Patient #4. RN 1 failed to remove gloves and perform hand hygiene before nor after care with differnt patients and their stations. 4. During an observation on 6/05/23 between 10:01 AM to 10:04 AM: Observed RN 1 move from Station #22 to Station #24 and used Alcohol-based hand sanitizer [ABHS] on their gloves, then went to Station #16, used ABHS over gloves again, walked back to Station #24, used ABHS again over gloves and back to Station #23. PCT 1 observed using ABHS over their gloves in		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 body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled. § *After contact with inanimate objects near the patient.* 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. § *After contact with other objects within the patient station or treatment space* § If hands are physically soiled and require soap and water the duration of the entire procedure should be 40-60 seconds. If decontaminating hands with alcohol-based hand rub the duration of the entire procedure should be 20- 30 seconds. o Staff should adhere to Personal Protective Equipment: § Face shields should be worn	

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	Station #15, walked to Station #24, reset the monitor, used ABHS again, reset Station #23 monitor, used ABHS over gloves again, walked to Station #18, reset monitor then removed gloves and performed ABHS. 5. During an observation on 6/05/23 at 10:43 AM, RN 1 failed to remove gloves and perform hand hygiene, before completing a CVC dressing change. RN 1 then walked to Station #24 to reset the monitor and back to Station #15. RN 1 failed to remove gloves and perform hand hygiene before care was resumed at Station #15. 6. During an interview on 6/05/23 at 12:44 PM, Corporate Person 1 confirmed gloves should be changed in between procedures and face shields should be worn when staff have the potential to come into contact with blood. 7. Review of Policy "Hand Hygiene," dated 3/17/23, indicated that hands will be decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water before and after direct contact with patients, immediately after removing gloves and after contact with other objects within the patient station or treatment space. 8. Review of Policy "Central Venous Catheter Dressing Change", dated 11/02/19, indicated hand hygiene and don clean gloves should be performed prior to cleaning the exit site with antiseptic product. 9. Review of Policy "Medication Preparation and Administration Procedure", dated 5/02/22 indicated hands should be washed and PPE be applied before administering medication.		down over eyes, face, and nose during patient care. Effective 6/26/2023, the Clinical Manager or designee will conduct weekly audits with focus ensuring hand hygiene is performed per facility policy by all staff, as well as, ensuring all staff have a face shield in place covering eyes, nose and mouth during possible blood or fluid spatter events. Per facility policy by staff by staff utilizing Infection Control Audit Tool for four weeks or until 100% compliance is achieved. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution	

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			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 7/6/2023.	
V 0147 Bldg. 00	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters. II. Surveillance A. Monitor the catheter sites visually of			

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	individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients. VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections]. Based on observation and interview, the dialysis facility failed to ensure staff followed policies and procedures related to Central Venous Cather (CVC) care for 2 of 2 observations of staff who performed CVC exit site care (PCT 1 and RN 1). Findings include: 1. During an observation on 6/05/23 at 9:38 AM, observed PCT 1 disinfected Patient #12's skin around CVC exit site. PCT 1 failed to cleanse the skin with antiseptic for at least 30 seconds. 2. During an observation on 6/05/23 at 10:43 AM, observed RN 1 disinfected Patient #15's skin around CVC exit site. RN 1 failed to cleanse the skin with antiseptic for at least 30 seconds. 3. During an interview on 6/05/23 at 12:44 PM, Corporate Person 1 indicated that it had been a while since they have worked with CVC's and they thought it should be cleansed for 20 seconds.	V 0147	**V 147 IC-STAFF EDUCATION-CATHERERS/CATHETER CARE** On 6/23/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: · Changing the Catheter Dressing Policy and Procedure Emphasis was placed on: · clean the catheter exit site: o **2% Chlorhexidine and 70% alcohol: Using gentle back and forth friction, clean the exit site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds and allow to dry a minimum of 30 seconds.** Effective 6/26/2023, the Clinical Manager or designee will conduct	07/06/2023

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	4. Review of Policy "Central Venous Catheter Dressing Change", dated 11/02/19, indicated the exit site should be cleaned with antiseptic product for 30 seconds and allow to dry.		weekly audits with focus ensuring during catheter dressing change the exit site will be cleaned with antiseptic product for 30 seconds and allow to dry per facility policy by staff utilizing Central Venous Catheter Exit Site Care Audit Tool for four weeks or until 100% compliance is achieved. Once compliance is sustained, the Governing Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the 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.	

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			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 07/06/2023.	
V 0405 Bldg. 00	494.60(c)(2) PE-COMFORTABLE TEMPERATURE The dialysis facility must: (i) Maintain a comfortable temperature within the facility; and (ii) Make reasonable accommodations for the patients who are not comfortable at this temperature. Based on observation, record review, and interview, the End Stage Renal Disease (ESRD) facility failed to ensure staff followed facility policies and procedures related to fistula and graft access for 1 of 1 flash tour observations of ESRD facility. Findings include: 1. During an observation on 06/05/23 at 09:38 AM, observed Patient #17 with access covered, and during an observation on 06/05/23 at 10:48 AM, observed Patient #12 and Patient #17 with access covered. 2. Review of policy 45284 "Patient Assessment	V 0405	**V 405 PE-COMFORTABLE TEMPERATURE** On 6/23/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Patient Assessment and Monitoring Emphasis was placed on: · All staff to ensure patient's access remains uncovered during treatment. Effective 6/26/2023, the Clinical Manager or designee will conduct daily audits with focus on ensuring	07/06/2023

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	and Monitoring," revised 05/01/23, indicated staff should have ensured access remained uncovered throughout treatment. 3. During an interview conducted on 6/05/23 at 12:44PM, Corporate Person 1 confirmed staff should ensure access sites were not covered during treatment.		the patient access is uncovered during the treatment for one week and then weekly for three weeks or until 100% compliance is achieved utilizing the Clinical Practice Checklist Audit Tool. 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 Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the 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	

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			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 07/06/2023.	
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 dialysis facility failed to follow their policy when they failed to ensure the patient's blood pressure (BP) was checked every 30 minutes during in-center hemodialysis (ICHD) and failed to ensure the registered nurse (RN) completed a timely pre-dialysis treatment assessment for 4 of 4 patient clinical records reviewed (Patients #3, 4, 7, and 14); failed to ensure hemodialysis access checks were performed every 30 minutes during ICHD for 2 of 4 patient records reviewed (Patient #4 and 7); failed to ensure machine settings for blood flow rate (BFR) and dialysate flow rate (DFR), were checked every 30 minutes during ICHD for 1 of 4 patient records reviewed (Patient #3); failed to ensure the RN notified the physician of a high BP for 1 of 1 patient records reviewed who had high BP readings during treatment (Patient #4); and failed to ensure patient's pre-dialysis standing BP was checked for 2 of 3	V 0543	**V 543 POC-MANAGE VOLUME STATUS** On 6/23/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Nursing Supervision and Delegation · Patient Assessment and Monitoring 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	07/07/2023

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	clinical records reviewed of patients who were able to stand (Patient #3 and 14.) Findings include: 1. Patient #4's hemodialysis treatment sheets, dated 5/17/23 - 6/02/23, were reviewed and evidenced the following: On 5/17/23, ICHD treatment began at 5:46 AM; the RN assessment was performed at 7:31 AM, 1 hour and 45 minutes after treatment began. The treatment sheets indicated the Patient was ambulatory; the record failed to evidence a standing BP check was performed. On 5/19/23, the treatment record indicated Patient was ambulatory; the record failed to evidence a pre-dialysis BP check was performed while Patient was standing. On 5/22/23, the ICHD treatment began at 5:50 AM; the RN assessment was performed at 7:45 AM, 1 hour and 55 minutes later. A BP check was completed at 8:03 AM with a follow-up BP check at 9:02 AM, 59 minutes later. The treatment sheet indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. On 5/24/23, a BP check was conducted at 8:34 AM; a follow-up BP check was conducted at 9:32 AM, 58 minutes later. The treatment sheet indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. On 5/26/23, ICHD treatment began at 5:44 AM; the RN pre-treatment assessment was performed at 7:24 AM, 1 hour and 40 minutes later. The		reported by the patient, or the patient was hospitalized, the registered nurse must assess the patient. o The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction. · The registered nurse must evaluate each patient preferably within an hour or according to state requirements. · Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations. o Report to the nurse: § Systolic blood pressures greater than 180 mm/Hg § Diastolic blood pressure greater than 100 mm/Hg § Blood Pressure less than or equal to 100 mm/hg systolic o Document any findings and interventions in the medical record. · Monitor patient Access every 30 minutes and document. · Observe connections are secure and visible. · If an external catheter is in use, observe and document that the HemaClip device is in place. · Ensure access remains uncovered throughout the treatment. · Observe and ensure: · Tape is secure	

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	treatment record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. A BP check was completed at 5:38 AM and indicated a BP of 198/97; at 5:47 AM, a BP of 202/91 was obtained; at 6:35 AM, indicated a BP of 193/95 was assessed; at 7:05 AM, a BP of 196/95 was obtained; at 7:34 AM, a BP of 201/90 was obtained; at 8:01 AM, a BP of 200/100 was obtained; at 8:35 AM, a BP of 206/100 was obtained; at 9:02 AM, a BP of 197/101 was obtained; at 9:36 AM, a BP of 183/102 was obtained, and at 9:47 AM, a BP of 191/103 was obtained. The record failed to evidence the RN notified the nephrologist of the high BP readings. On 5/29/23, the treatment record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. On 5/31/23, ICHD treatment began at 6:56 AM; the RN pre-treatment assessment was performed at 8:47 AM, 1 hour and 51 minutes later. The treatment record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. On 6/2/23, the ICHD treatment began at 5:55 AM; the RN pre-treatment assessment was performed at 8:18 AM, 2 hours and 23 minutes later. The treatment record indicated the Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. 2. Patient #14's hemodialysis treatment sheets, dated 5/17/23 - 6/2/23, were reviewed and evidenced the following: On 5/17/23, the ICHD treatment began at 9:32 AM;		· Needles are intact · **No bleeding or infiltration is noted** · 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: Check prescribed blood flow is being achieved or reason is documented in medical record if unable to meet prescribed blood flow. § Check dialysate flow rate setting is correct, and the prescribed flow is being delivered. Effective 6/26/2023, the Clinical Manager or designee will conduct weekly treatment sheet audits on 10% of completed treatments with focus on ensuring nursing assessments are completed timely, abnormal blood pressures reported to the RN, vital signs and safety checks are recorded every 30 minutes or not to exceed 45 minutes, per facility policy, BFR/DFR is achieved and maintained throughout the dialysis treatment for justification documented, and all ambulatory patients have a documented standing blood pressure pre/post treatment utilizing Treatment Sheet Audit Tool for four weeks or until 100% compliance is achieved. Once compliance is sustained, the Governing Body will	

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	the RN pre-treatment assessment was performed at 10:48 AM, 1 hour and 16 minutes later. A BP check was completed at 10:33 AM with a follow-up BP check at 11:32 AM, 59 minutes later. The treatment record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. On 5/19/23, a BP check was completed at 11:04 AM, a follow-up BP check was completed at 12:33 PM, 1 hour and 29 minutes later. The treatment record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. On 5/24/23, ICHD treatment sheets indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. On 5/26/23, ICHD treatment began at 9:42 AM; the RN pre-treatment assessment was performed at 11:31 AM, 1 hour and 49 minutes later. A BP check was completed at 9:42 AM with a follow-up BP check at 10:35 AM, 53 minutes later. The treatment record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. On 5/29/23, a BP check was completed at 11:03 AM, with a follow-up BP check completed at 12:01 PM, 58 minutes later. The treatment record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. On 6/02/23, ICHD treatment record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed.		decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the 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	

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	3. During an interview on 6/06/23 at 2:26 PM, Corporate Person 2 confirmed the findings for Patient's #4 and #14 were accurate and indicated BP checks, machine settings, and access checks should have been performed every 30 minutes with a grace period extending the time up to 45 minutes. Corporate Person 2 indicated the RN assessment should be completed within the first hour of ICHD treatment start time and indicated there was no documentation to evidence that the nephrologist was notified of Patient #4's elevated BP on 5/26/23 and indicated standing pre-treatment BP's should be performed if the patient was able to stand. 4. Patient #3's hemodialysis treatment sheets, dated 05/02/23 - 06/05/23, were reviewed and evidenced the following: On 05/22/23, Patient's BP and hemodialysis access site were checked at 11:00 AM with a follow-up BP and access check at 12:14 PM, 1 hour and 14 minutes later. Patient's machine settings were checked at 11:16 AM with a follow-up machine settings check at 12:14 PM, 58 minutes later. After the 12:14 PM machine settings check, the next follow-up machine settings check was at 1:14 PM, 1 hour later. The ICHD treatment record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. On 05/24/23, the ICHD treatment began at 10:50 AM; the RN assessment was performed at 12:22 PM, 1 hour and 32 minutes later. The treatment record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. The ICHD record, dated 05/26/23, indicated		minutes, education and monitoring documentation are available for review at the clinic. Completion 07/06/2023	

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	Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. The ICHD record, dated 05/29/23, indicated the BFR and DFR were not recorded at the start of treatment at 10:14 AM and was not recorded again until 12:02 PM, 1 hour and 48 minutes after start of treatment. BFR and DFR were checked at 12:37 PM with a recheck at 1:35 PM, 58 minutes later. The record indicated Patient was ambulatory and failed to evidence a pre-dialysis treatment standing BP check was performed. The ICHD record, dated 6/01/23, indicated treatment began at 7:27 AM; the RN pre-treatment assessment was performed at 10:24 AM, 2 hours and 57 minutes later. The record indicated Patient was ambulatory and failed to evidence a pre-dialysis standing BP check was performed. The ICHD record, dated 6/03/23, indicated Patient was ambulatory and failed to evidence a pre-dialysis standing BP check was performed. The ICHD record, dated 06/05/23, indicated Patient's BP was checked at 12:05 PM with a follow-up BP check at 1:05 PM, 1 hour later. The record indicated Patient was ambulatory and failed to evidence a pre-dialysis standing BP check was performed. 5. Patient #7's hemodialysis treatment sheets, dated 05/17/23 - 06/02/23, were reviewed and evidenced the following: On 5/17/23, Patient's BP was checked at 07:36 AM with a follow-up BP check at 08:33 AM, 57 minutes later.			

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	On 5/19/23, Patient's BP and hemodialysis access site were checked at 10:35 AM with follow-up BP and access checks at 11:44 AM, 1 hour and 9 minutes later. On 5/24/23, Patient's BP was checked at 09:40 AM with a follow-up BP check at 10:34 AM, 54 minutes later. The next follow-up BP check was at 11:31 AM, 57 minutes later. On 5/31/23, ICHD treatment began at 07:19 AM; the record failed to evidence a RN pre-treatment assessment was performed. On 6/02/23, ICHD treatment began at 6:29 AM; the record failed to evidence a RN pre-treatment assessment was performed. 6. During an interview on 6/06/2023 beginning at 3:28 PM, Corporate Person 2 confirmed the findings for Patient #4 and #7 were accurate and indicated BP checks, machine settings, and access checks should have been performed every 30 minutes with a grace period extending the time up to 45 minutes. Corporate Person 2 indicated RN pre-treatment assessments should have been completed and preferably completed within an hour of ICHD treatment start time and that standing pre-treatment BP should have been performed if the patient was able to stand. 7. Review of policy 45284 "Patient Assessment and Monitoring," revised 05/01/23, indicated staff should have checked BP and machine settings for BFR and DFR and should have performed safety checks including ensuring access secure and visible every 30 minutes or as needed during treatment, not to exceed 45 minutes. 8. Review of policy 45265 "Nursing Supervision			

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	and Delegation," revised 05/01/23, indicated the RN was required to evaluate each patient preferably within one hour of treatment start time. 9. Review of policy 45285 "Determination of Blood Pressure," revised 02/07/22, indicated for ICHD patients BP should have been taken with patient standing pre-dialysis and every 30 minutes. 10. Review of policy "Hypertension," dated 09/07/21, indicated staff should have recognized, reported, and immediately addressed systolic BP greater than 180 and/ or diastolic BP greater than 100.			
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 dialysis facility failed to ensure the dialysate flow rate (DFR) and/ or blood flow rate (BFR) were set according to physician orders for 4 of 4 patient records reviewed (Patient #3, 4, 7, and 14.) Findings include: 1. Review of policy 45284 "Patient Assessment and Monitoring," revised 05/01/23, indicated the BFR and DFR should have been checked every 30 minutes or more often not to exceed 45 minutes to ensure the BFR and DFR were at the prescribed rates. If prescribed BFR was not achieved, the staff member was to document the reason on the Treatment Sheet.	V 0544	**V 544 POC-ACHIEVE ADEQUATE CLEARANCE** On 6/23/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Patient Assessment and Monitoring Emphasis was placed on: · Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes, or per state regulations. o Check machine settings and measurements:	07/06/2023

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	2. Patient #3's record was reviewed and included a review of the Treatment Sheets dated 05/22/23 through 06/05/23. The record evidenced a physician ordered BFR of 400 and a physician ordered DFR of manual 600 during the dialysis treatments. On 05/22/23, the ordered DFR was manual 600. Patient's treatment began at 10:32 AM with a DFR of 500 and continued at that rate for the entire treatment. On 05/29/23, the ordered DFR was manual 600. Patient's treatment began at 10:14 AM. The first recorded DFR was 500 at 12:02 PM and ran at 500 the remainder of the treatment. On 06/02/23, the ordered BFR was 400. Patient's treatment began at 10:12 AM with a BFR of 300 and ran at 300 until it was changed to 400 at 1:05 PM. During an interview on 6/06/23 beginning at 3:28 PM, Corporate Person 2 confirmed the above BFRs and DFRs for Patient #3 and confirmed there was no documented reason for the deviation from the physician orders. Corporate Person 2 indicated the incenter hemodialysis [ICHD] treatments should run at the prescribed BFRs and DFRs unless there were physician orders to change the rates and indicated the reason for the change in BFR or DFR should be documented on the ICHD treatment record / sheet. 3. Patient #7's record was reviewed and included ICHD Treatment records dated 5/17/23 to 6/02/23. The record evidenced a physician ordered BFR of 450 and a DFR of manual 800 during the dialysis treatments.		§ Check prescribed blood flow is being achieved or reason is documented in medical record if unable to meet prescribed blood flow. § Check dialysate flow rate setting is correct, and the prescribed flow is being delivered. Effective 6/26/2023, the Clinical Manager or designee will conduct weekly treatment sheet audits on 10% of completed treatments with focus on ensuring the dialysate flow rate (DFR) and blood flow rate (BFR) are set according to physician order, or justification documented if unable to achieve for four weeks or until 100% compliance is achieved utilizing Treatment Sheet Audit Tool. 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 Tool per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the	

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	152634	A. BUILDING 00 B. WING	06/06/2023

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	On 5/17/23, the ordered BFR was 450. Patient's treatment began at 6:58 AM with a BFR of 500 and ran at 500 throughout the treatment. On 5/22/23, the ordered BFR was 450. Patient's treatment began at 6:45 AM with a BFR of 450. The BFR was increased to 500 at 7:32 AM and continued at 500 throughout the rest of the treatment with a note in the Treatment Sheet that the BFR was increased to the prescribed rate. Patient's record failed to evidence a physician order to increase the BFR to 500. On 5/26/23, the ordered DFR was 800. Patient's treatment began at 7:18 AM with a DFR of 700 and ran at 700 throughout the treatment. On 5/31/23, the ordered BFR was 450. Patient's treatment began at 7:19 AM with a BFR of 500 and continued at 500 throughout the treatment. On 6/02/23, the ordered BFR was 450. Patient's treatment began at 6:29 AM with a BFR of 500 and continued at 500. At 9:03 AM, BFR was changed to 475 and continued at 475 throughout the rest of the treatment. During an interview on 6/06/23 beginning at 3:28 PM, Corporate Person 2 confirmed the BFRs and DFRs for Patient #7 and confirmed there was no documented reason for the deviation from the physician orders. Corporate Person 2 indicated the treatments should have run at the prescribed BFRs and DFRs unless there were physician orders to change the rates and indicated the reason for the change in BFR or DFR should be documented on the Treatment Sheet. 4. Patient #4's hemodialysis treatment sheets, dated 5/17/23 - 6/2/23, were reviewed and		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 07/06/2023	

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	evidenced a physician ordered BFR of 400 and DFR of 600 ml / hour, with a total run time of 4 hours 0 minutes during the dialysis treatments. On 5/17/23, the treatment began at 5:46 AM with a BFR setting of 350 and ran at 350 for the entire treatment. The DFR setting was at 500 ml/hour and ran at 500 ml/hour for the entire treatment. On 5/29/23, the treatment began at 5:57 AM with a BFR setting of 400, then at 7:04 AM, began a BFR at 375 for the remainder of the treatment. On 5/31/23, the treatment began at 6:56 AM with a BFR setting of 350, then at 8:04 AM, began a BFR at 400 for the remainder of the treatment. The total run time was 2 hours and 55 minutes. During an interview on 6/06/23 beginning at 2:26 PM, the Corporate Employee 2 confirmed the above BFRs and DFRs for Patient #4 on the Treatment Sheets and indicated there was no documented reason for the deviation from the physician orders. The Corporate Employee 2 also indicated the treatments should have run at the prescribed BFRs and DFRs unless there were physician orders to change the rates and indicated the reason for the change in BFR or DFR should have been documented on the Treatment Sheet. 5. Patient #14's hemodialysis treatment sheets, dated 5/17/23 - 6/2/23, were reviewed and evidenced a physician ordered BFR of 400 and DFR of 800 ml/hour during the dialysis treatments. On 5/17/23, the treatment began at 9:32 AM with a DFR setting of 700 and ran at 700 for the entire treatment.			

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	During an interview on 6/06/23 beginning at 2:26 PM, the Corporate Person 2 confirmed the above BFRs and DFRs for Patient #14 on the Treatment Sheets and indicated there was no documented reason for the deviation from the physician orders.			
V 0559 Bldg. 00	494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must- (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section. Based on clinical record review and interview, the dialysis facility failed to ensure the Plan of Care (POC) was updated regarding missed visits for 1 of 4 clinical records reviewed. (Patient #14). Findings include: 1. Review of Patient #14's hemodialysis treatment record, dated 5/17/23 - 6/02/23 evidenced 2 missed dialysis treatments within the timeframe reviewed. The record failed to evidence documentation that the ESRD facility attempted to contact Patient #14 regarding their missed treatments and that the physician was notified. 2. The Clinical Manager provided the most recent	V 0559	**V 559 POC-OUTCOME NOT ACHIEVED-ADJUST POC** On 6/23/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Managing Missed Treatments due to Non-Adherence or Prolonged Hospitalization or Vacation · Quality Assessment and Performance Improvement Emphasis was placed on: · If the patient misses the regularly scheduled treatment and has not contacted the facility,	07/06/2023

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	POC dated 6/22/22; the POC failed to evidence a focus on missed visit or adherence to treatments. 3. Review of Policy "Managing Missed Treatments", published 7/05/22, indicated that if the patient misses the regularly scheduled treatment and has not contacted the facility, then the facility will attempt to locate the patient by calling the home number or emergency contact if necessary. If the patient is located, the facility will offer to reschedule the missed treatment if a slot is available. 4. During an interview on 6/06/23 at 2:26 PM, Corporate Person 2 indicated that the facility offers to reschedule the missed visit, notifies the physician and the RN educates the patient on the risks of missing treatment.		then: 1. Attempt to locate the patient by calling the home number or emergency contacts if necessary. 2. If the patient is located, offer to reschedule the missed treatment if a slot is available. 2b. If staff is unable to reach the patient or their emergency contact, notify the attending nephrologist of the patient's absence and inquire if it is known whether the patient was admitted to the hospital. Staff may also do the following to attempt to locate the patient and determine they are safe: (i). Check nearby hospitals to see if the patient was admitted. (ii). Contact the police to request they go to the patient's home to check on the patient. 3. Document the missed treatment and all actions taken to locate the patient in the medical record. 4. Refer the patient to the Social Worker who can utilize the Root Cause Analysis and Intervention Tool for Patients Not Meeting Quality Goals to assess reason for the missed treatment and if there's a barrier that might contribute to more misses in the future. 5. Social Worker reports assessment findings to Clinical Manager to determine a plan for	

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			preventing future missed treatments. Consult or notify attending nephrologist of any plan that is identified. 6**. Discuss the plan with the patient, update the plan of care if necessary and make any additional documentation in the medical record.** Effective 6/26/2023, the Clinical Manager or designee will review patient schedule daily with specific focus on patients who failed to treat as scheduled. If a patient has not contacted the facility, the clinical manager or designee will be responsible to attempt locating the patient. Documentation of the missed treatment, physician notification, and all actions taken to locate the patient will be noted in the medical record. Monitoring for continued compliance will be done monthly through the review of the Missed or Shorten treatment dashboard with a documented review of all Missed Treatments noted in the Social Worker QAI summary workbook in eQUIP. The QAPI Committee will monitor data/information; prioritize areas for improvement; determine potential root causes; develop, implement, evaluate, and revise action plans that result in sustainable improvements in patient care.	

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			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 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 07/06/2023	

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