STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	06/06/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

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E 0000 Bldg. 00	An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62. Survey Dates: 6/1/2022 to 6/7/2022 Census: 117 At this Emergency Preparedness survey, Fresenius Medical Care Gary, was found to have not been in compliance with the Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers, including staffing and the implementation of staffing during a pandemic at 42 CFR 494.62.	E 0000		
E 0028 Bldg. 00	494.62(b)(9) Dialysis Emergency Equipment §494.62(b)(9) Condition for Coverage: [(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:] (9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs,			

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

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	are on the premises at all times and immediately available. Based on observation, record review, and interview the facility failed to ensure all items in the emergency evacuation kit were maintained in accordance with manufactures instructions in 1 of 1 emergency crash carts used for in-center hemodialysis patients. The findings include: An agency policy titled "Emergency Medication, Equipment and Supplies," published 7/6/2020, stated " ... the following minimum emergency supplies and equipment must be on the premises at all times, clean, functional, accessible, and immediately available Automated External Defibrillator (AED) ... emergency medications ... The emergency cart must be checked monthly or after use for contents, expiration dates, cleanliness, and proper functioning of all equipment ... items approaching expiration must be reordered and replaced prior to the actual expiration date...." During an observation on 6/1/2022 at 10:00 AM, the AED was observed on the top of the code cart. The pads attached to the AED expired on 4/4/2022. During an observation on 6/1/2022 at 10:02 AM, emergency medications were observed locked in the code cart. There were two vials of 50% Dextrose (used for patients with low blood sugar) with an expiration date of 4/1/2022, 2 vials of sodium bicarbonate with an expiration date of 4/1/2022 and a bottle of NitroStat tablets (used for patients having a heart attack) with an expiration date of 5/31/2022.	E 0028	**E 028** On June 14, 2022, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Emergency Medication, Equipment and Supplies Policy version 5 Emphasis was placed on: · An emergency cart, sometimes called 'crash cart' contains emergency equipment and medications for medical emergencies such as a cardiac arrest. An emergency cart must be available in the facility as per the Conditions for Coverage. o The emergency cart must be: § Checked monthly or after use for contents, expiration dates, cleanliness, and proper functioning of all equipment. § An itemized log must be kept indicating the contents and expiration dates of contents. Items approaching expiration must be reordered and replaced prior to the actual expiration date. On June 1, 2022, all expired medications were removed from the emergency crash cart. Effective June 20, 2022, Clinical Manager or designee will conduct monthly audits with focus on ensuring all items in the emergency crash cart are within expiration dates and all expired	07/18/2022

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	During an interview on 6/1/2022 at 3:15 PM, the clinical manager indicated the dextrose and sodium bicarbonate were on back order, so they were keeping the expired vials on hand. She indicated there was not a written order from the physician to use the expired medication in case of an emergency. The clinical manager indicated the new bottle of nitroStat had come in and had not been added to the code cart, but instead was put in the medication cabinet.		medication is not available for patient use. Monitoring for continued compliance will be done monthly through the Clinic Audit Checklist per QAI calendar. Documentation of any back-ordered supplies will be noted in the QAI meeting minutes. 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 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 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	

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			of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion July 18,2022.	
V 0000 Bldg. 00		V 0000		
	This visit was for a CORE Federal recertification and complaint survey of an ESRD provider. Survey dates: 6/1/2022 to 6/7/2022 Complaint #: IN00315230 -unsubstantiated. Unrelated federal deficiencies were cited Complaint #: IN00314390 -unsubstantiated. Unrelated federal deficiencies were cited Census by Service Type: In-Center Hemodialysis: 98 Peritoneal Dialysis Patients: 19 Total Census: 117 Isolation Room/Waiver: yes Quality Review Completed 06/15/2022			
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.			

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	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 8 of 8 in-center hemodialysis records reviewed. (Patient #1, #2, #3, #4, #5, #6, #7, #8) 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. An agency document titled "Patient Assessment and Monitoring," published 9/29/2019, stated, " ... If the PCT/LPN notes any changes or abnormal findings in the patient's condition, the patient care technician must report the findings to the registered nurse who will further assess the patient. An abnormal finding confirmed by the RN will be reported to the attending physician ... record blood pressure and verify systolic blood pressures greater than 180 and/or diastolic blood pressures greater than 100 systolic pressures less than or equal to 100 during treatment Record pulse verify pulses manually if automated readings display below 60 or above 60 beats per minute...."	V 0504	**V 504** On June 14,2022, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Patient Assessment and Monitoring version 3 Emphasis was placed on: · Direct patient care staff may collect pre-treatment weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. o If the PCT/LPN notes any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the patient care technician MUST report the changes in the patient condition to a registered nurse who will further assess the patient prior to initiation of the treatment. o An abnormal finding confirmed by the RN will be reported to the attending physician for assessment and intervention, if necessary, as determined by the clinical judgement of the registered nurse. · Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations. o Record blood pressure. § Recheck blood pressures after	07/18/2022

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	4. Record review on 6/6/2022, for patient #1, start of care 10/16/2018, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/26/2022. This document indicated patient #1's blood pressure at 11:04 AM, was 175/101 (normal blood pressure reading is 120/80). This document failed to evidence the nurse was notified of patient #1's high blood pressure. Record review on 6/6/2022, for patient #1, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/24/2022. This document indicated patient #1's blood pressure at 11:24 AM, was 193/120. This document failed to evidence the nurse was notified of patient #1's high blood pressure. Record review on 6/6/2022, for patient #1, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/19/2022. This document indicated patient #1's blood pressure at 11:04 AM, was 166/100. This document failed to evidence the nurse was notified of patient #1's high blood pressure. Record review on 6/6/2022, for patient #1, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/13/2022. This document indicated patient #1's blood pressure at 3:00 PM, was 176/107, and at 5:32 PM, patient #1's blood pressure was 151/100. This document failed to evidence the nurse was notified of patient #1's high blood pressure. Record review on 6/6/2022, for patient #1, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/12/2022. This document indicated patient #1's blood pressure at 2:58 PM, was 143/107. This document failed to		a drop that requires interventions such as administering normal saline. § Reposition electronic cuff or use a manual cuff for aberrant blood pressure readings. 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 · Non-licensed staff may collect post-treatment weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. The staff member who collects the information and evaluates the patient post-treatment will document their findings on the hemodialysis treatment record. o If any changes or abnormal findings in the patient's condition, vital signs, or vascular access are observed or reported by the patient, the PCT/LPN MUST report the changes in the patient condition to a registered nurse who will further assess the patient prior to discharge after the treatment. o An abnormal finding confirmed by the RN will be reported to the attending physician, if necessary, as determined by the clinical judgement of the registered nurse for assessment and intervention.	

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	evidence the nurse was notified of patient #1's high blood pressure. 5. Record review on 6/6/2022, for patient #2, start of care 10/9/2021, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/10/2022. This document indicated patient #2's blood pressure at 1:33 PM, was 95/55. This document failed to evidence the nurse was notified of patient #2's low blood pressure. 6. Record review on 6/6/2022, for patient #3, start of care 11/8/2021, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/30/2022. This document indicated patient #3's blood pressure at 9:36 AM, was 95/80, and at 10:47 AM, patient #3's blood pressure was 96/55. This document failed to evidence the nurse was notified of patient #3's low blood pressure. Record review on 6/6/2022, for patient #3, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/25/2022. This document indicated patient #3's blood pressure at 10:00 AM, was 200/97, and at 10:30 AM, patient #3's blood pressure was 195/103. This document failed to evidence the nurse was notified of patient #3's high blood pressure. Record review on 6/6/2022, for patient #3, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/20/2022. This document indicated patient #3's blood pressure at 9:43 AM, was 201/92, and at 10:30 AM, patient #3's blood pressure was 201/94. This document failed to evidence the nurse was notified of patient #3's high blood pressure. Record review on 6/6/2022, for patient #3, evidenced an agency document titled, "Treatment		The Registered Nurse will assess/re-assess any findings addressed pre-treatment prior to discharge. Effective June 20, 2022, Clinical Manager or designee will conduct weekly treatment sheet audits on 10% of completed treatments with focus on ensuring patient pre/post and intradialytic blood pressures are assessed and managed utilizing Treatment Sheet Audit Form for 4 weeks or until 90% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the 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	

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	Sheet for Facility," dated 5/16/2022. This document indicated patient #3's blood pressure at 10:00 AM, was 201/92, and at 10:30 AM patient #3's blood pressure was 188/108, at 11:00 AM, patient #3's blood pressure was 194/101, at 11:33 AM patient #3's blood pressure was 208/101, at 12:01 PM, patient #3's blood pressure was 202/97, at 12:35 PM, patient #3's blood pressure was 191/101, at 1:03 PM, the patient's blood pressure was 209/99, and at 1:31 PM, the patient's blood pressure was 206/103. This document failed to evidence documentation the nurse notified the physician of patient #3's high blood pressure. Record review on 6/6/2022, for patient #3, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/13/2022. This document indicated patient #3's blood pressure at 10:00 AM, was 214/93, at 10:34 AM, patient #3's blood pressure was 215/99, at 11:01 AM, patient #3's blood pressure was 202/107, at 11:34 AM, patient #3's blood pressure was 196/104, at 12:01 PM, patient #3's blood pressure was 202/97, at 1:01 PM, patient #3's blood pressure was 205/97, and at 1:39 PM, the patient's blood pressure was 207/108. This document failed to evidence the nurse notified the physician of patient #3's high blood pressure. 7. Record review on 6/6/2022, for patient #4, start of care 12/1/2012, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/26/2022. This document indicated patient #4's blood pressure at 8:59 AM, was 142/102. This document failed to evidence the nurse was notified of patient #4's high blood pressure. Record review on 6/6/2022, for patient #4, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/26/2022. This		findings, and take 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 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. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion July 18,2022.	

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	document indicated patient #4's blood pressure at 8:03 AM, was 152/101. This document failed to evidence the nurse was notified of patient #4's high blood pressure. 8. Record review on 6/6/2022, for patient #5, start of care 1/6/2020, evidenced an agency document titled, "Treatment Sheet for Facility," dated 6/1/2022. This document indicated patient #5's blood pressure at 5:25 AM, was 142/104. This document failed to evidence the nurse was notified of patient #5's high blood pressure. Record review on 6/6/2022, for patient #5, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/30/2022. This document indicated patient #5's blood pressure at 7:35 AM, was 91/59. This document failed to evidence the nurse was notified of patient #5's low blood pressure. Record review on 6/6/2022, for patient #5, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/20/2022. This document indicated patient #5's blood pressure at 7:11 AM, was 70/45 and at 8:02 AM, patient #5's blood pressure was 91/57. This document failed to evidence the nurse was notified of patient #5's low blood pressure. Record review on 6/6/2022, for patient #5, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/18/2022. This document indicated patient #5's blood pressure at 6:38 AM, was 97/58, at 7:33 AM, patient #5's blood pressure was 98/54, and at 8:31 AM, patient #5's blood pressure was 90/53. This document failed to evidence the nurse was notified of patient #5's low blood pressure.			

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	9. Record review on 6/6/2022, for patient #6, start of care 4/21/2022, evidenced an agency document titled, "Treatment Sheet for Facility," dated 4/28/2022. This document indicated patient #6's blood pressure at 11:00 AM, was 87/46, at 12:33 PM, patient #6's blood pressure was 78/32, and at 1:31 PM, patient #6's blood pressure was 96/40. This document failed to evidence the nurse was notified of patient #6's low blood pressure. Record review on 6/6/2022, for patient #6, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/3/2022. This document indicated patient #6's blood pressure at 11:00 AM, was 97/56. This document failed to evidence the nurse was notified of patient #6's low blood pressure. Record review on 6/6/2022, for patient #6, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/10/2022. This document indicated patient #6's blood pressure at 10:38 AM, was 95/59, and at 12:39 PM, patient #6's blood pressure was 87/57. This document failed to evidence the nurse was notified of patient #6's low blood pressure. Record review on 6/6/2022, for patient #6, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/10/2022. This document indicated patient #6's blood pressure at 11:04 AM, was 92/46, and at 11:31 PM, patient #6's blood pressure was 97/53. This document failed to evidence the nurse was notified of patient #6's low blood pressure. 10. Record review on 6/6/2022, for patient #7, start of care 1/18/2018, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/27/2022. This document indicated patient #7's			

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	blood pressure at 12:30 PM, was 139/102, at 1:03 PM, patient 7's blood pressure was 144/100, and at 1:36 PM, patient #7's blood pressure was 165/101. This document failed to evidence the nurse was notified of patient #7's high blood pressure. Record review on 6/6/2022, for patient #7, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/23/2022. This document indicated patient #7's blood pressure at 11:57 AM, was 190/110, at 12:38 PM, patient 7's blood pressure was 174/103, at 1:31 PM, patient #7's blood pressure was 203/114, at 2:00 PM patient #7's blood pressure was 161/103, and at 2:34 PM, patient #7's blood pressure was 180/106. This document failed to evidence the nurse was notified of patient #7's high blood pressure. Record review on 6/6/2022, for patient #7, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/20/2022. This document indicated patient #7's blood pressure at 11:40 AM, was 162/104, at 12:05 PM, patient 7's blood pressure was 154/105, at 1:34 PM, patient #7's blood pressure was 160/114, and at 2:02 PM, patient #7's blood pressure was 150/108. This document failed to evidence the nurse was notified of patient #7's high blood pressure. Record review on 6/6/2022, for patient #7, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/16/2022. This document indicate patient #7's blood pressure at 12:37 PM, was 166/102, at 1:07 PM, patient 7's blood pressure was 172/101, at 1:39 PM, patient #7's blood pressure was 165/109, and at 2:04 PM patient #7's blood pressure was 173/109, and at 2:29 PM, patient #7's blood pressure was 166/114. This document failed to evidence the nurse was notified of patient #7's high blood pressure.			

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	Record review on 6/6/2022, for patient #7, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/13/2022. This document indicated patient #7's blood pressure at 12:32 PM, was 194/105, at 1:02 PM, patient 7's blood pressure was 171/106, at 1:31 PM, patient #7's blood pressure was 154/116, and at 2:01 PM patient #7's blood pressure was 167/105, and at 2:31 PM, patient #7's blood pressure was 160/108. This document failed to evidence the nurse was notified patient #7's high blood pressure. Record review on 6/6/2022, for patient #7, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/9/2022. This document indicated patient #7's blood pressure at 1:02 PM, was 155/105 This document failed to evidence the nurse was notified of patient #7's high blood pressure. Record review on 6/6/2022, for patient #7, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/6/2022. This document indicated patient #7's blood pressure at 11:22 AM, was 180/105, at 12:31 PM, patient 7's blood pressure was 167/104, at 1:02 PM, patient #7's blood pressure was 171/107, and at 1:39 PM patient #7's blood pressure was 187/105, and at 2:22 PM, patient #7's blood pressure was 171/109. This document failed to evidence the nurse was notified of patient #7's high blood pressure. Record review on 6/6/2022, for patient #7, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/2/2022. This document indicated patient #7's blood pressure at 11:22 AM, was 180/105, at 12:31 PM, patient 7's blood pressure was 167/104, at 1:02 PM, patient #7's blood pressure was 171/107, at 1:39 PM, patient			

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	#7's blood pressure was 187/105, and at 2:22 PM, patient #7's blood pressure was 171/109. This document failed to evidence the nurse was notified of patient #7's high blood pressure. Record review on 6/6/2022, for patient #7, evidenced an agency document titled, "Treatment Sheet for Facility," dated 4/29/2022. This document indicated patient #7's blood pressure at 11:53 AM, was 174/105, at 12:41 PM, patient 7's blood pressure was 164/108, at 2:05 PM, patient #7's blood pressure was 160/102, at 2:30 PM, patient #7's blood pressure was 172/100, and at 2:55 PM, patient #7's blood pressure was 170/111. This document failed to evidence the nurse was notified of patient #7's high blood pressure. Record review on 6/6/2022, for patient #7, evidenced an agency document titled, "Treatment Sheet for Facility," dated 4/25/2022. This document indicated patient #7's blood pressure at 11:12 AM, was 190/109, at 11:33 AM, patient #7's blood pressure was 182/113, at 12:01 PM, patient #7's blood pressure was 185/110, at 12:32 PM, patient #7's blood pressure was 185/119, at 1:03 PM, patient #7's blood pressure was 179/119, and at 1:36 PM, patient #7's blood pressure was 191/117. This document failed to evidence the nurse was notified of patient #7's high blood pressure. 11. Record review on 6/6/2022, for patient #8, start of care 2/15/2020, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/26/2022. This document indicated patient #8's blood pressure at 2:01 PM, was 96/52. This document failed to evidence the nurse was notified of patient #8's low blood pressure. Record review on 6/6/2022, for patient #8,			

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	evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/24/2022. This document indicated patient #8's blood pressure at 11:30 AM, was 94/53, at 12:10 PM, patient #8's blood pressure was 83/53, at 12:30 PM, patient #8's blood pressure was 93/49, and at 1:05 PM, patient #8's blood pressure was 94/52. This document failed to evidence the nurse was notified of patient #8's low blood pressure. Record review on 6/6/2022, for patient #8, evidenced an agency document titled, "Treatment Sheet for Facility," dated 5/19/2022. This document indicated patient #8's blood pressure at 2:01 PM, was 125/109. This document failed to evidence the nurse was notified of patient #8's high blood pressure. 12. During an interview on 6/7/2022 at 12:38 PM, the clinical manager indicated if the blood pressure was greater than 180 systolic or greater 100 diastolic staff would need to alert the nurse. She also indicated if the systolic blood pressure was less than 100 and the diastolic less than 60 the nurse should be notified.			
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 8 in-center hemodialysis patients' clinical records reviewed. (patient #1, #2,	V 0543	**V 543** On June 14,2022, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:	07/18/2022

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	#3) The findings include: 1. An agency policy titled "Volume Management in ESRD [End Stage Renal Disease] Patients on Hemodialysis" published 9/7/2021, stated "If any of the following patient clinical conditions occur refer to the volume algorithm if applicable or consult with the physician for appropriate fluid interventions: ... Pre-treatment weight is less than or equal to EDW [estimated dry weight] .... EDW order should be updated post-treatment adjustments and patient fluid status ... The assessment of EDW remains 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...." 3. Clinical record review on 6/6/2022, for patient #1, start of care 10/16/2018, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/31/2022. This document indicated patient #1's dry weight [a weight without excess fluid] was 73 kilograms (kg). At the completion of treatment patient #1's weight was 76.9 kg. This document failed to evidence the physician was informed patient #1 failed to achieve her target dry		· Volume Management in ESRD Patients on Hemodialysis Policy version 1 · Patient Assessment and Monitoring version 3 Emphasis was placed on: · Direct patient care staff may collect pre-treatment weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. o If the PCT/LPN notes any changes or abnormal findings in the patient's condition or vascular access are observed or reported by the patient, or the patient was hospitalized, the patient care technician MUST report the changes in the patient condition to a registered nurse who will further assess the patient prior to initiation of the treatment. o An abnormal finding confirmed by the RN will be reported to the attending physician for assessment and intervention, if necessary, as determined by the clinical judgement of the registered nurse. · During nursing rounds, the Registered Nurse will review the data collected above and assess the following parameters as needed: o Review data collected above. Determine if any clinical interventions are necessary. Review the previous treatment data on the Fluid Assessment	

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	weight. Clinical record review on 6/6/2022, for patient #1, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/28/2022. This document indicated patient #1's dry weight was 73 kg. At the completion of treatment patient #1's weight was 78.7 kg. This document failed to evidence the physician was informed patient #1 failed to achieve her target dry weight. Clinical record review on 6/6/2022, for patient #1, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/26/2022. This document indicated patient #1's dry weight was 73 kg. At the completion of treatment patient #1's weight was 82.5 kg. This document failed to evidence the physician was informed patient #1 failed to achieve her target dry weight. Clinical record review on 6/6/2022, for patient #1, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/24/2022. This document indicated patient #1's dry weight was 73 kg. At the completion of treatment patient #1's weight was 95.3 kg. This document failed to evidence the physician was informed patient #1 failed to achieve her target dry weight. Clinical record review on 6/6/2022, for patient #1, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/19/2022. This document indicated patient #1's dry weight was 73 kg. At the completion of treatment patient #1's weight was 86 kg. This document failed to evidence the physician was informed patient #1 failed to achieve her target dry weight. Clinical record review on 6/6/2022, for patient #1, evidenced an agency document titled "Treatment		Tab. § The nurse should ask the patient if they have had shortness of breath, chest pain or cough, cramping, loss of appetite or vomiting or diarrhea. o Auscultate lung sounds. o Assess the patient for edema. o Document findings and interventions in the medical record. Contact the physician as needed for additional orders based on assessment findings and clinical judgement. · Non-licensed staff may collect post-treatment weight, BP, pulse, respirations, temperature, general observations, access, and complaints reported by the patient. o The staff member who collects the information and evaluates the patient post-treatment will document their findings on the hemodialysis treatment record. If any changes or abnormal findings in the patient's condition, vital signs, or vascular access are observed or reported by the patient, the PCT/LPN MUST report the changes in the patient condition to a registered nurse who will further assess the patient prior to discharge after the treatment. o An abnormal finding confirmed by the RN will be reported to the attending physician, if necessary, as determined by the clinical judgement of the registered nurse	

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	Sheet for Facility" dated 5/17/2022. This document indicated patient #1's dry weight was 73 kg. At the completion of treatment patient #1's weight was 86.1 kg. This document failed to evidence the physician was informed patient #1 failed to achieve her target dry weight. Clinical record review on 6/6/2022, for patient #1, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/14/2022. This document indicated patient #1's dry weight was 73 kg. At the completion of treatment patient #1's weight was 82.1 kg. This document failed to evidence the physician was informed patient #1 failed to achieve her target dry weight. Clinical record review on 6/6/2022, for patient #1, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/13/2022. This document indicated patient #1's dry weight was 73 kg. At the completion of treatment patient #1's weight was 83 kg. This document failed to evidence the physician was informed patient #1 failed to achieve her target dry weight. During an interview on 6/7/2022 at 12:38 PM, the clinical manager indicated patient #1 was a chronic fluid abuser and they want to get her to a good weight so they have not changed her dry weight. 3. Clinical record review on 6/6/2022, for patient #2, start of care 10/19/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/19/2022. This document indicated patient #2's dry weight was 73 kg. At the completion of treatment patient #2's weight was 71.1 kg. This document failed to evidence the physician was informed patient #2 failed to achieve his target dry weight.		for assessment and intervention. The Registered Nurse will assess/re-assess any findings addressed pre-treatment prior to discharge. Effective June 20, 2022 Clinical Manager or designee will conduct weekly treatment sheet audits on 10% of completed treatments with focus on ensuring the physician is aware of the inability of patients to achieve their dry weight to establish the appropriateness of the dialysis prescription utilizing Treatment Sheet Audit Form for 4 weeks or until 90% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the 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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	Clinical record review on 6/6/2022, for patient #2, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/17/2022. This document indicated patient #2's dry weight was 73 kg. At the completion of treatment patient #2's weight was 71.3 kg. This document failed to evidence the physician was informed patient #2 failed to achieve his target dry weight. Clinical record review on 6/6/2022, for patient #2, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/14/2022. This document indicated patient #2's dry weight was 73 kg. At the completion of treatment patient #2's weight was 70.3 kg. This document failed to evidence the physician was informed patient #2 failed to achieve his target dry weight. During an interview on 6/7/2022 at 12:45 PM, the clinical manager indicated patient #2's dry weight will need to be recalculated. 4. Clinical record review on 6/6/2022, for patient #3, start of care 11/8/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/30/2022. This document indicated patient #3's dry weight was 83.5 kg. At the completion of treatment patient #3's weight was 87.1 kg. This document failed to evidence the physician was informed patient #3 failed to achieve her target dry weight. Clinical record review on 6/6/2022, for patient #3, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/25/2022. This document indicated patient #3's dry weight was 83.5 kg. At the completion of treatment patient #3's weight was 84.7 kg. This document failed to evidence the physician was informed patient #3 failed to		of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. 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. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion July 18, 2022.	

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	achieve her target dry weight. Clinical record review on 6/6/2022, for patient #3, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/23/2022. This document indicated patient #3's dry weight was 83.5 kg. At the completion of treatment patient #3's weight was 82.1 kg. This document failed to evidence the physician was informed patient #3 failed to achieve her target dry weight. Clinical record review on 6/6/2022, for patient #3, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/20/2022. This document indicated patient #3's dry weight was 83.5 kg. At the completion of treatment patient #3's weight was 81.7 kg. This document failed to evidence the physician was informed patient #3 failed to achieve her target dry weight. Clinical record review on 6/6/2022, for patient #3, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/16/2022. This document indicated patient #3's dry weight was 83.5 kg. At the completion of treatment patient #3's weight was 82.4 kg. This document failed to evidence the physician was informed patient #3 failed to achieve her target dry weight. Clinical record review on 6/6/2022, for patient #3, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/16/2022. This document indicated patient #3's dry weight was 83.5 kg. At the completion of treatment patient #3's weight was 85.4 kg. This document failed to evidence the physician was informed patient #3 failed to achieve her target dry weight. During an interview on 6/7/2022 at 1:16 PM, the clinical manager indicated patient #3 was a			

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	chronic fluid abuser and the dry weight was correct.			
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 prescriptions orders were verified and adhered to in order to achieve and sustain the prescribed dose of dialysis to meet the adequacy of dialysis in 7 out of 8 in-center hemodialysis records reviewed. (#1, #2, #3, #4, #5, #6, #8) 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 6/6/2022, for patient #1, start of care 10/16/2018, evidenced agency documents titled "Treatment Sheet for Facility" dated 5/28/2022, 5/26/2022, and 5/13/2022. These documents indicated the patient's prescribed BFR (blood flow rate) was 450 ml/min (milliliters/minute). During these treatments, patient #1's BFR was 400 ml/min. These documents failed to evidence why patient #1 did	V 0544	**V 544** On June 14, 2022, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Patient Assessment and Monitoring version 3 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. § 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: June 20, 2022, Clinical Manager or designee will conduct weekly treatment sheet audits on 10% of completed treatments with focus on ensuring the physician	07/18/2022

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	not get her prescribed treatment. Clinical record review on 6/6/2022 for patient #1, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/19/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #1's BFR at 10:25 AM, was 400 ml/min, and from 11:04 AM, to the completion of treatment at 2:21 PM, patient #1's BFR was 475 ml/min. This document failed to evidence why patient #1 did not get her prescribed treatment. 3. Clinical record review on 6/6/2022, for patient #2, start of care 10/19/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/31/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #2's BFR was 350 ml/min. This document failed to evidence why patient #2 did not get his prescribed treatment. Clinical record review on 6/6/2022, for patient #2, start of care 10/19/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/28/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #2's BFR was 400 ml/min. This document failed to evidence why patient #2 did not get his prescribed treatment. Clinical record review on 6/6/2022, for patient #2, start of care 10/19/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/26/2022. This document indicated the patient's prescribed DFR (dialysate flow rate) was 600 ml/min. During this treatment patient #2's DFR was 500 ml/min. This document failed to evidence why patient #2 did not get his prescribed treatment.		order for Blood Flow Rate (BFR) and Dialysate Flow Rate (DFR) were achieved and sustained throughout the dialysis treatment utilizing Treatment Sheet Audit Form for 4 weeks or until 90% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the 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 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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	Clinical record review on 6/6/2022, for patient #2, start of care 10/19/2021, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/21/2022. This document indicated the patient's prescribed BFR was 450 ml/min and his prescribed DFR was 600 ml/min. During this treatment patient #2's BFR was 400 ml/min, and his DFR was 800 ml/min. This document failed to evidence why patient #2 did not get his prescribed treatment. Clinical record review on 6/6/2022, for patient #2, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/12/2022. This document indicated the patient's prescribed DFR was 600 ml/min. During this treatment patient #2's DFR was 800 ml/min. This document failed to evidence why patient #2 did not get his prescribed treatment. 4. Clinical record review on 6/6/2022, for patient #3, start of care 11/8/2021, evidenced agency documents titled "Treatment Sheet for Facility" dated 5/11/2022 This document indicated the patient's prescribed BFR was 450 ml/min, and the DFR was 500 ml/min. During this treatment patient #3's BFR was 400 ml/min, and her DFR was 800 ml/min. This document failed to evidence why patient #3 did not get her prescribed treatment. Clinical record review on 6/6/2022, for patient #3, evidenced agency documents titled "Treatment Sheet for Facility" dated 5/30/2022, 5/18/2022, and 5/13/2022. These documents indicated the patient's prescribed DFR was 500 ml/min. During these treatments, patient #3's DFR was 800 ml/min. These documents failed to evidence why patient #3 did not get her prescribed treatment.		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. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion July 18, 2022	

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	152501	A. BUILDING 00 B. WING	06/06/2022

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	Clinical record review on 6/6/2022 for patient #3, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/27/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #3's BFR at 9:30 AM, was 300 ml/min, and from 11:00 AM, to the completion of treatment at 1:38 PM, patient #3's BFR was 400 ml/min. This document failed to evidence why patient #3 did not get her prescribed treatment. 5. Clinical record review on 6/6/2022, for patient #4, start of care 12/1/2012, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/31/2022, 5/28/2022, and 5/24/2022. These documents indicated the patient's prescribed DFR was 500 ml/min. During these treatments, patient #4's DFR was 800 ml/min. These documents failed to evidence why patient #4 did not get his prescribed treatment. 6. Clinical record review on 6/6/2022, for patient #5, start of care 1/6/2020, evidenced an agency document titled "Treatment Sheet for Facility" dated 6/1/2022, 5/20/2022, 5/18/2022 and 5/13/2022. These documents indicated the patient's prescribed DFR was 500 ml/min. During these treatments, patient #5's DFR was 800 ml/min. These documents failed to evidence why patient #5 did not get his prescribed treatment. Clinical record review on 6/6/2022, for patient #5, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/27/2022. This document indicated the patient's prescribed BFR was 500 ml/min. During this treatment patient #5's BFR was decreased to 425 ml/min. This document failed to evidence why patient #5's BFR was decreased. Clinical record review on 6/6/2022, for patient #5,			

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	start of care 10/19/2021, evidenced agency documents titled "Treatment Sheet for Facility" dated 5/16/2022 and 5/11/2022. These documents indicated the patient's prescribed BFR was 500 ml/min. During these treatments, patient #5's BFR was 450 ml/min. These documents failed to evidence why patient #5 did not get his prescribed treatment. 7. Clinical record review on 6/6/2022, for patient #6, start of care 4/21/2022, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/3/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #6's BFR was 250 ml/min. This document failed to evidence why patient #6 did not get his prescribed treatment. Clinical record review on 6/6/2022, for patient #6, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/5/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #6's BFR was 300 ml/min. This document failed to evidence why patient #6 did not get his prescribed treatment. Clinical record review on 6/6/2022, for patient #6, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/7/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #6's BFR was 300 ml/min. This document failed to evidence why patient #6 did not get his prescribed treatment. Clinical record review on 6/6/2022, for patient #6, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/10/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #6's BFR was 175 ml/min. This document failed to evidence why			

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	patient #6 did not get his prescribed treatment. Clinical record review on 6/6/2022, for patient #6, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/12/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #6's BFR was 250 ml/min. This document failed to evidence why patient #6 did not get his prescribed treatment. Clinical record review on 6/6/2022, for patient #6, evidenced an agency document titled "Treatment Sheet for Facility" dated 5/28/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #6's BFR was 500 ml/min. This document failed to evidence why patient #6 did not get his prescribed treatment. 8. Clinical record review on 6/6/2022, for patient #8, start of care 2/15/2020, evidenced an agency document titled "Treatment Sheet for Facility" dated 6/2/2022. This document indicated the patient's prescribed BFR was 450 ml/min. During this treatment patient #8's BFR was 300 ml/min. This document failed to evidence why patient #8 did not get his prescribed treatment. Clinical record review on 6/6/2022, for patient #8, start of care 2/15/2020, evidenced an agency document titled "Treatment Sheet for Facility" dated 6/2/2022. This document indicated the patient's prescribed DFR was 500 ml/min. During this treatment patient #8's DFR was 800 ml/min. This document failed to evidence why patient #8 did not get her prescribed treatment. 9. During an interview on 6/7/2022 at 12:55 PM, the clinical manager indicated the DFR and BFR should be run as prescribed by the physician. She indicated if the staff cannot run the patient as			

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	prescribed they need to document as to why and notify the nurse and/or physician.			
V 0551 Bldg. 00	494.90(a)(5) POC-VA MONITOR/PREVENT FAILURE/STENOSIS The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. Based on observation, record review and interview, the facility failed to ensure the patient's access site was monitored for symptoms of stenosis in 4 out of 6 observations of initiating dialysis with a fistula. (PCT 1, PCT 2) The findings include: 1. An agency policy titled "Access Assessment and Cannulation," published 8/22/2018, stated " ... Check fistula for adequate bruit and thrill to confirm patency ... Listen: bruit high pitch whistle bruit not present throughout access ... document...." 2. During an observation on 6/1/2022 at 10:07 AM, PCT [patient care technician] 1, was observed at station #7 initiating dialysis for patient #10. PCT 1 failed to use a stethoscope and auscultate patient #10's access. 3. During an observation on 6/1/2022 at 10:15 AM, PCT 2 was observed at station #13 initiating dialysis for patient #11. PCT 2 failed to use a stethoscope and auscultate patient #11's access. 4. During an observation on 6/2/2022 at 10:20 AM, PCT 1 was observed at station #18 initiating dialysis for patient #12. PCT 1 failed to use a	V 0551	**V 551** On June 14,2022, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Access Assessment and Cannulation Procedure version 2 Emphasis was placed on: · Clean stethoscope with alcohol. o LISTEN: § Bruit high pitch/whistle § Bruit not present throughout access o Document in treatment record. Effective June 20,2022, Clinical Manager or designee will conduct visual audits weekly with focus on ensuring the patients access site is monitored for symptoms of stenosis utilizing Access Assessment Audit Form for 4 weeks or until 90% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI	07/18/2022

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	stethoscope and auscultate patient #12's access. 5. During an observation on 6/2/2022 at 11:11 AM, PCT 1 was observed at station #19 initiating dialysis for patient #13. PCT 1 failed to use a stethoscope and auscultate patient #13's access. During an interview on 6/2/2022 at 12:17 PM, the clinical manager indicated the staff should auscultate the access every treatment.		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 to provide oversight, review findings, and take 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 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. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion July 18, 2022.	

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V 0676 Bldg. 00	494.130 LAB-CLIA LABS/MEET NEEDS OF PTS The dialysis facility must provide or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter. Based on observation, record review, and interview the facility failed to ensure proper temperature control of the laboratory refrigerator on 4 of 5 survey days. The findings include: 1. Review of documents from Laboratory A evidenced blood samples must be refrigerated and kept at 36 to 46 degrees Fahrenheit 2. During an observation on 6/1/2022 at 10:15 AM, the laboratory refrigerator was observed to be at 29 degrees Fahrenheit and there were 11 lavender top tubes of blood in the refrigerator. 3. During an observation on 6/2/2022 at 10:20 AM, the laboratory refrigerator was observed to be at 49 degrees Fahrenheit and there were 4 lavender top tubes of blood in the refrigerator. 4. During an observation on 6/3/2022 at 11:25 AM, the laboratory refrigerator was observed to be at 29 degrees Fahrenheit. 5. During an observation on 6/7/2022 at 12:11 PM, the laboratory refrigerator was observed to be new, and the temperature was at 29 degrees Fahrenheit.	V 0676	**V 676** On June 14, 2022, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Spectra Laboratories Diagnostic Specimen Collection Guide Rev. 6/13b Emphasis was placed on: · Prior to specimen collection, check the expiration date on all supplies. Note that tubes expire the last day of the expiration month. · Refrigerate (36º - 46ºF) Effective June 20, 2022 Clinical Manager or designee will conduct audits of the lab refrigerator log with focus on ensuring the temperature remains within range utilizing Technical Maintenance System (TMS) Laboratory Refrigerator Temperature Log under Clinic Logs 3 times/week for 4 weeks or until 90% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on	07/18/2022

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	During an interview on 6/1/2022 at 3:56 PM, the clinical manager indicated she could not recall what temperature the refrigerator should be kept at. During an interview on 6/2/2022 at 11:35 AM, the clinical manager indicated the refrigerator temperature was probably high because the staff was going in and out of it. She indicated she called the lab and was informed as long as the labs did not freeze, they should be okay. During an interview on 6/3/2022 at 2:32 PM, the clinical manager indicated they were going to get a new refrigerator for the labs During an interview on 6/7/2022 at 11:02 AM, the clinical manager indicated the door may not have been closed properly and caused the temperature to go above the normal range for the labs.		compliance. Once compliance sustained monitoring will be done monthly per the QAI calendar with review of the TMS Laboratory Refrigerator Temperature Log under Technical Logs completed by the Biomedical Technician. The Biomedical Technician will document any findings in the Technical Workbook in eQUIP with any noncompliance being discussed in QAI and documented in the monthly meeting minutes. 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 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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