STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152591	A. BUILDING 00 B. WING	11/10/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE TERRE HAUTE SOUTH	315 E SPRINGHILL DR TERRE HAUTE, IN 47802

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
E 0000 Bldg. 00	An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62 Survey Dates: 11/5/2021-11/10/2021 Facility Number: 004839 Census = 22 in-center hemodialysis No home hemodialysis No home peritoneal dialysis At this Emergency Preparedness survey, Fresenius Medical Care Terre Haute North was found not in compliance with Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers, 42 CFR 494.62 QR Completed 11/22/2021 A4	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:]			

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

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	(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, are on the premises at all times and immediately available. Based on observation, record review, and interview, the facility failed to maintain emergency medication and supplies according to manufacturer instructions for 1 of 1 crash carts observed; and failed to maintain emergency supplies according to manufacturer instructions for 1 of 1 emergency evacuation box observed. Findings include: 1. A revised July 6, 2020 policy titled, "Emergency Medication, Equipment and Supplies" was provided by the Clinic Manager of Entity 2, a separate licensed dialysis facility, on 11/8/2021 at 1:10 p.m. The policy indicated, but was not limited to, "Emergency cart ... The emergency cart must be: ... Checked monthly ... for ... expiration dates ... Items approaching expiration must be reordered and replaced prior to the actual expiration date.... Emergency Evacuation Box ... Items approaching expiration must be reordered and replaced prior to the actual expiration date...." 2. During the flash tour observation on 11/5/2021 at 9:10 a.m., two boxes containing 10 vials each of Calcium Chloride 10%-1 gram/10 ml (milliliter) with an expiration date 10/21 were observed in the crash cart emergency drug kit; two luer lock cap set MPC 125 with an expiration date 7/25/21, and a luer lock cap set MPC 125 with an expiration date 6/27/21 were observed in the top drawer of the	E 0028	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Emergency Medication, Equipment and Supplies Emphasis was placed on: · Ensuring emergency supplies are immediately available for use including but not limited to Calcium Chloride 10%-1 gram/10 ml, luer lock cap sets MPC 125, Yankauer suction instruments, 0.2 micron disk filters, and Providone-Iodine medium prep pads. · Utilization of the emergency supply monthly checklist to identify all contents in the emergency cart. · Include the expiration date of supplies on the monthly checklist. · Items approaching expiration must be reordered and replaced prior to the actual expiration date. Effective November 29, 2021, the Clinic Manager or designee will conduct an emergency supply audit weekly for one month utilizing the Emergency Cart Checklist. The focus will be on	12/09/2021

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	crash cart; and a Yankauer suction instrument with an expiration date 11/21/20, and two, 0.2 micron disk filters with an expiration date 2/2017 were observed in the second drawer from the top of the crash cart. A box of Providone-Iodine medium prep pads with an expiration date of 8/2017 were observed in the emergency evacuation box. 3. During an interview on 11/5/2021 at 3:45 p.m., the Clinic Manager of Entity 2 was made aware of the expired medication and supplies and no additional information was provided.		removing expired supplies and ensuring all emergency supplies are immediately available for use. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinic Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review.	

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			The Clinic Manager is responsible for overall compliance. Date of Completion: December 9, 2021	
V 0000 Bldg. 00		V 0000		
	This survey was for a federal ESRD recertification in conjunction with a Covid-19 infection control survey. Survey Dates: 11/5/2021-11/10/2021 Facility Number: 004839 Census: 22 in-center hemodialysis No home hemodialysis No home peritoneal dialysis			
V 0113 Bldg. 00	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.			
	Based on observation, record review, and interview, the facility failed to ensure hand hygiene was performed effectively for 2 of 3 medication preparation and administration observations (RN B). Findings include: 1. A revised November 1, 2021 policy titled, "Medication Preparation and Administration" was provided by the Clinic Manager of Entity 2, a	V 0113	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Medication Preparation and Administration · Hand Hygiene Education emphasis was placed on: · Perform hand hygiene prior to handling vials and preparing or	12/09/2021

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	separate licensed dialysis facility, on 11/8/2021 at 1:10 p.m. The policy indicated, but was not limited to, "Infection Control. The following steps must be taken to ensure infection control. Perform hand hygiene prior to ... handling vials ... and preparing or administering medications...." 2. During an observation on 11/8/2021 at 9:45 a.m., RN B failed to perform hand hygiene prior to dispensing Cincalcet (lowers calcium) tablets into two medication cups for patient #10 and #11 during medication preparation. RN B failed to perform hand hygiene, took both medication cups containing Cincalcet tablets into dialysis station 7, sat the medication cup on the chairside table for patient #10, failed to perform hand hygiene, and took the second medication cup into dialysis station 8, and sat the medication cup on the chairside table for patient #11. 3. During an observation on 11/8/2021 at 10:36 a.m., RN B failed to perform hand hygiene prior to Hecterol (lowers parathyroid hormone) multi-dose vial medication preparation. 4. During an interview on 11/8/2021 at 3:54 p.m., the Clinic Manager of Entity 2 was made aware of the observations and indicated hand hygiene should be performed before medication preparation and administration.		administering medications. · Practice hand hygiene between each patient and station to prevent cross-contamination. Effective November 29, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on practicing hand hygiene during medication prep and administration to improve infection control. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to	

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			provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 9, 2021	
V 0117 Bldg. 00	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to			

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	deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients. Based on observation, record review, and interview, the facility failed to ensure medications were delivered separately to each patient for 1 of 3 medication administration observations (RN B). Findings include: 1. A revised November 1, 2021 policy titled, "Medication Preparation and Administration" was provided by the Clinic Manager of Entity 2, a separate licensed dialysis facility, on 11/8/2021 at 1:10 p.m. The policy indicated, but was not limited to, "Medications shall be ... delivered separately to each patient...." 2. During an observation on 11/8/2021 at 9:45 a.m., RN B took two medication cups containing Cinacalcet tablets for patient #10 and #11, into dialysis station 7, sat one medication cup on the chairside table for patient #10, and took the remaining medication cup for patient # 11 into dialysis station 8, and sat it on the chairside table. 3. During an interview on 11/8/2021 at 3:54 p.m., the Clinic Manager of Entity 2 was made aware of the observation and indicated oral medications for different patients should be taken into the dialysis station separately and not together.	V 0117	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Medication Preparation and Administration Education emphasis was placed on: · Ensure medications are delivered separately to each patient. Effective November 29, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on delivering medications to each patient separately per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit	12/09/2021

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			results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 9, 2021	
V 0122 Bldg. 00	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated			

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	surfaces, medical devices, and equipment. Based on observation, record review, and interview, the facility failed to follow applicable infection control procedures when cleaning and disinfecting contaminated surfaces for 1 of 2 dialysis stations being cleaned (Station # 6). Findings include: 1. A revised November 2, 2020 policy titled, "Cleaning and Disinfection of the Dialysis Station" was provided by the Clinic Manager of Entity 2, a separate licensed dialysis facility, on 11/8/2021 at 1:10 p.m. The policy indicated, but was not limited to, "General Cleaning. The dialysis station could become contaminated with blood and other body fluids during treatment. After use, all non-disposable equipment ... must be disinfected with 1:100 bleach ... Work Surface Cleaning and Disinfection w/out Visible Blood using Bleach Solutions. All work surfaces shall be cleaned and disinfected with 1:100 bleach solution after completion of procedures...." 2. During an observation on 11/8/2021 at 11:33 a.m., during cleaning and disinfection of the dialysis station, PCT C failed to disinfect the television and countertop behind the dialysis station. 3. During an interview on 11/8/2021 at 3:54 p.m., the Clinic Manager of Entity 2 was made aware of the observation. The Clinic Manager indicated the countertop behind the dialysis station was considered a clean area an should be disinfected after each patient. No additional information was provided.	V 0122	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Cleaning and Disinfection of the Dialysis Station Education emphasis was placed on: · Cleaning and disinfected all work surfaces within the hemodialysis station with 1:100 bleach solution after completion of procedures; including but not limited to the back chase counter and television. · Ensure the surfaces are glistening wet and allow to air dry before placing the next patient into the hemodialysis station. Effective November 29, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be cleaning all work surfaces within the hemodialysis station with 1:100 bleach solution per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.	12/09/2021

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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 to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 9, 2021	
V 0143 Bldg. 00	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques			

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	when dispensing and administering intravenous medications from vials and ampules; and Based on observation, record review, and interview, the facility failed to label opened, multi-dose vials and opened medication bottles for 1 of 1 medication preparation room observations; and failed to ensure a new, sterile syringe and needle was used to enter a multi-dose vial for 1 of 3 medication preparation observations (RN B). Findings include: 1. A revised November 1, 2021 policy titled, "Medication Preparation and Administration" was provided by the Clinic Manager of Entity 2, a separate licensed dialysis facility, on 11/8/2021 at 1:10 p.m. The policy indicated, but was not limited to, "Labeling Vials. When preparing medications if the vial is not used immediately in its entirety, the nurse ... must place the date and time the vial was opened on the mediation label along with their initials. Note: To ensure all open vials are properly marked, the nurse must never walk away from an opened, multi-dose vial without writing the date and time the vial was opened. Label any open multi-dose vial that is not used immediately ... Infection Control. The following steps must be taken to ensure infection control.... Always use a sterile syringe and needle when entering a vial.... If either vial is multi-use a different syringe must be used for entry into each vial...." 2. During the flash tour observation on 11/5/2021 at 9:10 a.m., an opened, unlabeled, multi-dose vial of Hecterol (reduces parathyroid hormone) 4 mcg (microgram)/2 ml (milliliters), lot # BRM063,	V 0143	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Medication Preparation and Administration Education emphasis was placed on: · Expiration dates for all stored medications are to be monitored on a monthly basis. · Expired medications will be discarded promptly. · The person opening medication bottles and vials is responsible to initial and date at the time of opening. · Always use a new sterile syringe and needle when entering a vial or ampule. Effective November 29, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on correct labeling of the medication bottles & vials when opened, ensuring expired medications are discarded, and single syringe usage per vial per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality	12/09/2021

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	expiration date 3/2023, was observed on the countertop in the locked medication preparation room. Opened, unlabeled bottles of Cincalcet (lowers calcium)60 mg tablets, lot # PB00721 with an expiration date 8/22, lot # PB00722 with an expiration date of 8/22, and an opened bottle of Acetaminophen (pain reliever) 325 mg tablets, lot # 101T07 with an expiration date 10/22, were observed on the bottom shelf of the cabinet labeled "medications" in the locked medication preparation room. During an interview on 11/5/2021 at 12:00 p.m., RN B indicated that open, multi-dose vials should be labeled with initials, date, and time on the label. RN B indicated he/she forgot to label Hecterol when he/she opened the vial. RN B indicated multi-dose vials without labels must be discarded and cannot be reused. During an interview on 11/5/2021 at 3:45 p.m., the Clinic Manager of Entity 2 was made aware of the observations and indicated open bottles of medication and multi-dose vials should be initialed, dated, and timed when opened. 3. During an observation on 11/5/2021 at 12:00 p.m., RN B was observed to withdraw Hecterol from an opened, multi-dose vial using a new, sterile syringe and needle. RN B opened a new multi-dose vial of Hecterol and used the same needle and syringe filled with mediation from the opened, multi dose vial to withdraw and add medication from the new multi-dose vial. During an interview on 11/5/2021 at 3:45 p.m., the Clinic Manager of Entity 2 was made aware of the observation and indicated a different syringe should be used for each of the multi-dose vials. The Clinic Manager of Entity 2 indicated		Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 9, 2021	

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FRESENIUS MEDICAL CARE TERRE HAUTE SOUTH	315 E SPRINGHILL DR TERRE HAUTE, IN 47802

(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
	medication from the multi-dose vials should be drawn into two separate syringes and not combined into one.			
V 0250 Bldg. 00	494.40(a) DIALYS PROPORT-MONITOR PH/CONDUCTIVITY 5.6 Dialysate proportioning: monitor pH/conductivity It is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method before starting the treatment of the next patient. Based on observation, record review, and interview, the facility failed to ensure staff were knowledgeable of set limits for allowable pH variability for 1 of 2 pH test observations. Findings include: 1. A revised August 2, 2020 policy titled, "Checking Conductivity and pH of Final Dialysate" was provided by the Clinic Manager of Entity 2, a separate licensed dialysis facility, on 11/8/2021 at 1:10 p.m. The policy indicated, but was not limited to, "Conductivity and pH of dialysate are measurements used to verify proper proportioning of acid concentrate, bicarbonate concentrate and treated water.... Responsibility. Fresenius Kidney Care (FKC) Staff ... In dialysis, many fluids are routinely monitored for pH as a quality measurement.... Dialysate pH Range. The range at which the test method can display pH values within the Association for the Advancement of Medical Instrumentation (AAMI) recommendation for dialysate pH of 6.9-7.6.... The final ... pH must be tested prior to	V 0250	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Checking Conductivity and pH of Final Dialysate Education emphasis was placed on: · Ensure proper proportioning of acid concentrate, bicarbonate concentrate, and treated water. · The dialysate range must be verified with an instrument at which the test method can display pH values within the Association for the Advancement of Medical Instrumentation (AAMI) recommendation for dialysate pH of 6.9-7.6. · The final dialysate pH must be tested prior to each patient's treatment to verify the value is within the set parameters.	12/09/2021

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	each patient's treatment.... If any of the following scenarios occurs the reason must be investigated and reported to the clinical manager, charge nurse, team leader ... The dialysate pH is not within or equal to 6.9 to 7.6...." 2. During an observation on 11/8/2021 at 10:40 a.m., PCT D was observed to test the dialysate pH with the Phoenix meter for station 14. The test area did not contain signs or information to remind staff of the allowable pH variability. 3. During an interview on 11/8/2021 at 10:43 a.m., PCT D was unable to verbalize the allowable pH variability range. PCT D stated, "[BioMed] is who I ask if I'm unsure." PCT D indicated the facility had a sheet that listed the pH range but PCT D was unable to locate the sheet. 4. During an interview on 11/8/2021 at 3:54 p.m., the Clinic Manager of Entity 2 was made aware of the observation and no additional information was provided.		· If the dialysate pH is not within or equal to the set parameters of 6.9-7.6, the reason must be investigated and reported to the clinical manager, charge nurse, team leader. · Staff must verbalize the expected pH range and ensure patient safety prior to initiating dialysis. Effective November 29, 2021, the Clinical Manager or designee conduct dialysate pH audits daily for one week, then five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Patient Safety Monitoring Tool. The focus will be on verifying dialysate pH per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at	

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			each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 9, 2021	
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 follow their policy and ensure the PCT (patient care technician) notified a licensed nurse of BP (blood pressure) not within parameters for 4 of 5 patient records reviewed (Patients #5, 7, 12, & 14). Findings include:	V 0543	On November 23, 2021, the Clinical Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on the following policy: · Patient Assessment and Monitoring Education emphasis was placed	12/09/2021

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	1. A September 29, 2018 policy titled, "Patient Assessment and Monitoring" was provided by the Clinic Manager of Entity 2, a separate licensed dialysis facility, on 11/9/2021 at 11:24 a.m. The policy indicated, but was not limited to, "Monitoring During Treatment ... Blood Pressure.... Report to the nurse: Systolic [top number] blood pressure greater than 180 mm/Hg [millimeters of Mercury]. Diastolic [bottom number] blood pressure greater than 100 mm/Hg. Blood pressure less than or equal to 100 mm/Hg systolic...." 2. The complete clinical record for patient # 5 was reviewed on 11/9/2021, included 7 treatment sheets dated 10/22/2021 to 11/5/2021, and evidenced the following: A 11/1/2021 treatment sheet indicated a BP (blood pressure) reading of 92/49 at 11:03 a.m., noted by PCT C. At 11:28 a.m., the BP was 96/51, noted by PCT C. At 11:45 a.m., the BP was 98/47, noted by PCT D. At 12:03 p.m., the BP was 94/49, noted by PCT D. At 12:22 p.m., the BP was 91/43, noted by PCT D. At 12:43 p.m., the BP was 83/44, noted by PCT C. At 1:07 p.m., the BP was 89/43, noted by PCT D. At 1:30 p.m., the BP was 89/43, noted by PCT C, and the comments indicated, "Green AMP Light; Denies Complaints; Access Visible; pt states [he/she] feels fine/normal avls." [sic] At 2:02 p.m., the BP was 96/49, noted by PCT D. There was no indication the licensed nurse was notified of systolic blood pressures less than 100 mm/Hg. A 11/5/2021 treatment sheet indicated a BP reading of 87/46 at 1:43 p.m., noted by PCT C. At 1:44 p.m., the BP was 90/45, noted by PCT C, and the comments indicated, "Green AMP Light;		on: · Ensuring vital signs and treatment status of the patient are monitored every 30 minutes or more frequently if indicated during dialysis treatment and obtaining manual Blood Pressures (BPs) when needed. · The Patient Care Technician (PCT) is required to notify the RN for Diastolic Blood Pressure (DPB) greater than 100 mm/Hg and Systolic Blood Pressure (SBP) greater than 180 mm/Hg. · The PCT is required to notify the Registered Nurse (RN) for a SBP less than or equal to 100 mm/Hg. · The RN is responsible to document in the medical record of BPs out of parameters with an assessment and intervention when indicated. Effective November 29, 2021, the Clinic Manager or designee will conduct hemodialysis treatment sheet audits on a minimum of ten patient records daily for two weeks, then weekly for four weeks, then every two weeks for one month utilizing the Patient Treatment Sheet Monitoring Tool. The focus will be on PCT notification and RN assessments and interventions for BPs outside of set parameters. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI)	

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	Denies Complaints; Access Visible." At 1:59 p.m., the BP was 90/45, noted by PCT C. There was no indication the licensed nurse was notified of systolic blood pressures less than 100 mm/Hg. 3. The complete clinical record for patient # 7 was reviewed on 11/9/2021, included 7 treatment sheets dated 10/22/2021 to 11/5/2021, and evidenced the following: A 10/25/2021 treatment sheet indicated a BP reading of 99/53 at 6:42 a.m., noted by PCT C. There was no indication the licensed nurse was notified of the systolic blood pressure less than 100 mm/Hg. A 10/27/2021 treatment sheet indicated a BP reading of 94/50 at 7:05 a.m., noted by PCT D. At 7:36 a.m., the BP was 86/44, noted by PCT D. At 7:48 a.m., the BP was 88/44, noted by PCT D. At 8:06 a.m., the BP was 99/48, noted by PCT D. At 8:24 a.m., the BP was 93/45, noted by PCT D. There was no indication the licensed nurse was notified of systolic blood pressures less than 100 mm/Hg. A 11/3/2021 treatment sheet indicated a BP reading of 95/56 at 9:02 a.m., noted by PCT D. There was no indication the licensed nurse was notified of the systolic blood pressure less than 100 mm/Hg. 4. The complete clinical record for patient # 12 was reviewed on 11/9/2021, included 7 treatment sheets dated 10/25/2021 to 11/8/2021, and evidenced the following: A 10/25/2021 treatment sheet indicated a BP reading of 183/125 at 12:05 p.m., noted by PCT D. At 12:31 p.m., the BP was 97/58, noted by PCT D.		calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 9, 2021	

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	At 1:46 p.m., the BP was 86/48, noted by PCT D. At 2:04 p.m., the BP was 95/53, noted by PCT D. At 2:50 p.m., the BP was 99/60, noted by PCT C. At 3:09 p.m., the BP was 91/52, noted by PCT D. There was no indication the licensed nurse was notified of diastolic blood pressure greater than 180 mm/Hg and systolic blood pressures less than 100 mm/Hg. A 11/8/2021 treatment sheet indicated a BP reading of 198/111 at 12:03 p.m., noted by PCT D. At 12:24 p.m., the BP was 185/105, noted by PCT D. There was no indication the licensed nurse was notified of diastolic blood pressures greater than 180 mm/Hg. 5. The complete clinical record for patient # 14 was reviewed on 11/9/2021, included 3 treatment sheets dated 11/1/2021 to 11/5/2021, and evidenced the following: A 11/1/2021 treatment sheet indicated a BP reading of 94/52 at 11:48 a.m., noted by PCT D. At 12:25 p.m., the BP was 98/63, noted by PCT C. At 1:20 p.m., the BP was 98/56, noted by PCT C. There was no indication the licensed nurse was notified of systolic blood pressures less than 100 mm/Hg. A 11/5/2021 treatment sheet indicated a BP reading of 94/43 at 7:22 a.m., noted by PCT D. At 7:41 a.m., the BP was 95/51, noted by PCT D. At 8:20 a.m., the BP was 95/55, noted by PCT C. At 8:40 a.m., the BP was 88/50, noted by PCT C, and the comments indicated, "Access Visible; yellow olc; pt is complains of leg pain and back pain; rn aware." [sic] At 9:21 a.m., the BP was 84/55, noted by PCT D. There was no indication the licensed nurse was notified of systolic blood pressures less than 100 mm/Hg.			

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	6. During an interview on 11/9/2021 at 3:05 p.m., the Clinic Manager of Entity 2 was made aware of the patient record review findings and no additional information was provided.			
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 and interview, the facility failed to ensure lab supplies used to collect specimens from dialysis patients were not expired for 1 of 1 facility. Findings include: 1. A revised July 6, 2020 policy titled, "Emergency Medication, Equipment and Supplies" was provided by the Clinic Manager of Entity 2, a separate licensed dialysis facility, on 11/8/2021 at 1:10 p.m. The policy indicated, but was not limited to, "Items approaching expiration must be reordered and replaced prior to the actual expiration date...." 2. During the flash tour observation on 11/5/2021 at 9:10 a.m., 80, 3.5 ml BD vacutainer SST (blood collection tubes) with an expiration date 10/31/2021, and 61, 8.5 ml BD vacutainer SST with an expiration date 10/31/2021 were observed in the lab supplies drawer at the nurse's station.	V 0676	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Emergency Medication, Equipment and Supplies · Laboratory Testing Education emphasis was placed on: · Items approaching expiration must be reordered and replaced prior to the actual expiration date. · Ensure lab supplies used to collect specimens from dialysis patients are not expired. Effective November 29, 2021, the Clinic Manager or designee will conduct a lab supply audit weekly for one month utilizing the Patient Safety Monitoring Tool. The focus will be on removing expired supplies and ensuring all lab	12/09/2021

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	3. During an interview on 11/5/2021 at 3:45 p.m., the Clinic Manager of Entity 2 was made aware of the expired lab supplies and no additional information was provided. 4. During an interview on 11/8/2021 at 2:43 p.m., the Clinic Manager of Entity 2 indicated there was no policy for general expired supplies, and general supplies expiration dates would fall under the guidelines of the Emergency Medications, Equipment and Supplies policy.		supplies are immediately available for use. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	

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			Completion Date: December 9, 2021	
V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on observation, record review, and interview, the Medical Director failed to ensure all policies and procedures relative to patient care, infection control, and safety were adhered to by all individuals who treated patients in the facility. Findings include: 1. The Medical Director failed to ensure adherence to policies and procedures for staff hand hygiene (see tag V113). 2. The Medical Director failed to ensure adherence to policies and procedures to ensure medications were delivered separately to each patient (see tag V117). 3. The Medical Director failed to ensure adherence to policies and procedures for cleaning and disinfecting dialysis treatment stations (see tag V122). 4. The Medical Director failed to ensure adherence to policies and procedures for preparing and labeling opened medications (see tag V143).	V 0715	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Emergency Medication, Equipment and Supplies · Medication Preparation and Administration · Cleaning and Disinfection of the Dialysis Station · Patient Assessment and Monitoring · Laboratory Testing Education emphasis was placed on: · Ensuring all policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers. Effective November 29, 2021, the Clinic Manager or designee will	12/09/2021

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	5. The Medical Director failed to ensure adherence to policies and procedures for notifying a licensed nurse of BP (blood pressure) not within parameters (see tag V543). 6. The Medical Director failed to ensure adherence to policies and procedures for verifying lab supplies used to collect specimens from dialysis patients were not expired (see tag V676).		conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on practicing hand hygiene during medication prep and administration; correct labeling of the medication bottles & vials when opened, ensuring expired medications are discarded, and single syringe usage per vial; cleaning all work surfaces within the hemodialysis station with 1:100 bleach solution; delivering medications to each patient separately. Effective November 29, 2021, the Clinic Manager or designee will conduct hemodialysis treatment sheet audits on a minimum of ten patient records daily for two weeks, then weekly for four weeks, then every two weeks for one month utilizing the Patient Treatment Sheet Monitoring Tool. The focus will be on PCT notification and RN assessments and interventions for BPs outside of set parameters. Effective November 29, 2021, the Clinic Manager or designee will conduct a lab supply audit weekly for one month utilizing the Patient Safety Monitoring Tool. The focus will be on removing expired supplies and ensuring all lab supplies are immediately available for use.	

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