

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 012500	(X3) Date Survey Completed 09/16/2021
Name of Provider or Supplier Fmc Capitol City	Street Address, City, State 255 South Jackson Street, Montgomery, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies (Each deficiency should be preceded by full regulatory or LSC identifying information)
E0000	A recertification survey was completed on 9/14/21 to 9/16/21. FMC Capitol City was in substantial compliance for all emergency preparedness requirements.
V0000	Core Based on the recertification survey conducted 9/14/21 to 9/16/21 FMC Capitol City was not in compliance with the Conditions for Coverage (CfC) at 494.30 Infection Control and 494.90 Patient Plan of Care and related standard level deficiencies. Complaint number AL 00041511 was also investigated and the complaint was substantiated and standard level deficiencies were cited.
V0101	<p>COMPLIANCE WITH FED/STATE/LOCAL LAWS CFR(s): 494.20</p> <p>The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.</p> <p>This STANDARD is not met as evidenced by: Based on review of facility adverse event/ unusual occurrence report documentation and interview with the staff, it was determined the facility failed to follow State Licensure rules for End Stage Renal Disease for reporting unusual occurrences to the SSA (State Survey Agency). This had the potential to negatively affect all patients admitted to the facility. Findings include: Rules of Alabama State Board of Health Alabama Department of Public Health Chapter 420-5-5 Amended December 18, 2007 page 7 420-5-5-.01 General (7) Unusual Occurrences Unusual occurrences which threaten the welfare, safety and health of patients, personnel or visitors shall be reported by the ESRD (End Stage Renal Disease) facility within 24 hours, either by telephone (and confirmed in writing), or by facsimile to the Alabama Department of Public Health, Division of Health Care Facilities, and other agencies/authorities as required. Examples of unusual occurrences include: misuse of medical devices or</p>

medications, defective devices, suspected cases of patient abuse or neglect, life threatening burns, fires or other catastrophic occurrences, medical conditions or deaths that occur as the result of unusual circumstances. Any acute event that results in a patient receiving emergency treatment must be reported. Emergency treatment includes unscheduled transportation to a hospital or receipt of cardiac life support from a hospital, ambulance service or rescue squad, or staff member. Also to be reported are outbreaks of infectious disease or any condition in the facility, including the water treatment system, which would necessitate the temporary or long term closure of the dialysis facility (excluding inclement weather). 1. Review of the unusual occurrence circumstances on 9/16/21 at 9:15 AM with Employee Identifier (EI) # 1, Clinic Manager, revealed a patient had a sustained loss of consciousness at the facility during treatment on 9/2/21 and the patient was transferred to a hospital. The surveyor asked EI # 1 if the event was reported to the SSA. EI # 1 stated she/he would check with the charge nurse to see if it was reported. During an interview on 9/16/21 at 10:15 AM, EI # 1 confirmed the facility had failed to report the required unusual occurrence such as facility to hospital transfer to the SSA.

V0110

CFC-INFECTION CONTROL
CFR(s): 494.30

This CONDITION is not met as evidenced by:
Based on observations, facility policies and procedures and interviews, it was determined the facility failed to ensure the staff followed infection control requirements per regulations and facility policies and procedures. Refer to V101, V 111, V 113, V 122, V 126, V 130, and V 143

V0111

IC-SANITARY ENVIRONMENT
CFR(s): 494.30

The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.

This STANDARD is not met as evidenced by:
Based on observation, review of facility policy and procedures and interviews, it was determined the facility failed to ensure the staff: 1. Completed vascular access care according to facility procedure. 2. Emptied the prime bucket in the utility hopper or dirty sink according to facility policy. 3. Covered the bleach container with an opaque lid and discarded bleach solution daily at the end of the treatment day per facility procedure. This did affect Patient Identifier (PI) # 12, 1 of 2 patients observed for Access of AV (Atrioventricular) Fistula or Graft, and 1 of 2 observations conducted for cleaning and disinfection of the dialysis station and had the potential to affect all patients in this facility. Findings Include: Facility Procedure: Access Assessment and Cannulation Published: 8/22/2018 Version: 1 Purpose: The purpose of this procedure is to provide guidance for placement of needles in an AV (Arteriovenous) Fistula or AV Graft to obtain access to the circulatory system for hemodialysis. Assessment of Vascular Access... Step 1. Prior to treatment, ask your patient to wash access area with liquid soap for one minute, rinsing well... Wash access (per above), if patients unable to clean their access. Facility Policy: Use of Priming Buckets Published: 07/17/2017 Version: 4 Purpose: All facilities will utilize a priming bucket or approved

container to collect the Normal Saline prime pretreatment. Policy: A priming bucket or other approved removable container will be used to collect the normal saline prime pretreatment... Procedure: Step 4: At the completion of the patient treatment, remove the priming bucket or approved removable container, and dispose of the Normal Saline in the utility room hopper or dirty sink. Facility Procedure: Mixing Bleach Published: 08/25/2020 Version: 4 Procedure: 5. Cover opaque container with lid. 6. Discard solution daily at end of treatment day or more often if needed. 1. During observations of care on 9/14/21 from 10:25 AM until 11:15 AM at POD (section) 6, the surveyor observed the 1:100 (1 part bleach 100 parts water) bleach container uncovered. Staff had failed to secure the bleach container lid. In an interview on 9/16/21 at 10:30 AM, Employee Identifier (EI) # 1, Clinic Manager, confirmed staff failed to follow the facility bleach procedure. 2. An observation was conducted on 9/14/21 at 10:15 AM to observe EI # 7, Registered Nurse (RN), perform cleaning and disinfection of dialysis station 27. EI # 7 removed all bloodlines from the dialysis station and discarded in the biohazardous waste container. EI # 7 proceeded to remove his/her gloves, perform hand hygiene, and apply new gloves. EI # 7 then removed the prime bucket from station 27 and emptied the Normal Saline in the prime bucket into the wall drain behind the dialysis station. EI # 7 failed to empty the Normal Saline in the utility room hopper or dirty sink as directed per the policy. An interview was conducted on 9/16/21 at 8:40 AM with EI # 1 who stated the prime bucket should be emptied in the dirty sink. EI # 1 verified the staff failed to follow the facility policy for disposing of Normal Saline in the prime bucket. 3. During observation of care on 9/14/21 at 11:15 AM, the surveyor observed PI # 12 enter the treatment floor, walk to the scales, then walk directly to station 20. EI # 8, Certified Clinical Hemodialysis Technician, palpated the access site, then cleaned the area with alcohol, and cannulated the site. EI # 8 failed to wash the access with soap and water prior to starting the procedure, per policy. During an interview on 9/16/21 at 8:40 AM with EI # 1 verified the staff failed to complete vascular access care according to facility procedure. 30952 4. On 9/14/21 at 2:45 PM a tour of the isolation unit and interview was conducted with EI # 6, RN, Charge Nurse. The surveyor observed a bleach container 1/2 full of a clear liquid solution. The surveyor asked EI # 6 when staff should discard the bleach solution? EI # 6 reported bleach should be discarded at the end of the day. EI # 6 confirmed staff failed to discard the bleach Monday 9/13/21. EI # 6 promptly discarded the bleach solution from the bleach container into the dirty sink. In an interview on 9/16/21 at 10:30 AM, EI # 1 confirmed staff failed to follow the facility bleach procedure.

V0113

IC-WEAR GLOVES/HAND HYGIENE
CFR(s): 494.30(a)(1)

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.

This STANDARD is not met as evidenced by:
Based on observations, review of facility policies and procedure, staff interviews, it was determined the facility failed to ensure: 1. Patient's performed hand hygiene when entering the treatment floor 2. Staff performed hand hygiene before preparing Intravenous (IV) medications. 3. Staff sanitized hands for at least 20 seconds as per facility procedure. This did affect Patient Identifier (PI) # 12, 1 of 2 patients observed for Access of AV (Atrioventricular) Fistula or Graft, and PI # 2, PI # 14, 2 of 3 observations conducted for medication preparation and administration. This had the

potential to negatively affect all patient's dialyzing at this facility. Findings include:

Facility Policy: Hand Hygiene Published: 11/4/19 Version: 6 Purpose: The purpose of this policy is to prevent transmission of pathogenic microorganisms to patients and staff through cross contamination. Responsibility All staff, patients...must follow the same requirements for hand hygiene. Policy: Hand hygiene includes either washing hands with soap and water or using a waterless alcohol-based antiseptic hand rub with 60-90% alcohol content... ..below identifies when hands should be washed specifically with soap and water or when alcohol-based hand rubs can be used: ...

Entering and leaving the treatment room. Before performing any invasive procedure such as vascular access cannulation or administration of parental medications. Facility Hand Hygiene Procedure Published: 9/16/18 Reference Number: 47665 Procedure for Decontaminating Hands with Alcohol Based Hand Rubs 2. Apply Alcohol-based hand rubs to the palm of one hand... 3. Rub hands together covering all surfaces of the hands and fingers until hands are dry. Allowing alcohol to dry completely allows adequate contact time to kill germs... Note: Duration of the entire procedure: 20-30 seconds

Facility Policy: Medication Preparation and Administration Published: 04/05 /2021 Version: 6 "Purpose: To administer medications with the goals of staff and patient safety, optimal therapeutic response, and infection control. Infection Control Perform hand hygiene prior to accessing supplies, handling vials and IV solutions and preparing and administering medications. Aseptic technique will be used to prepare and administer IV medications.

1. During observations of care on 9/14/21 at 9:35 AM station 15, Employee Identifier (EI) # 4, Registered Nurse (RN), reinfused the extracorporeal circuit, removed gloves and sanitized hands for 7 seconds before donning clean gloves. EI # 4 failed to sanitize hands for at least 20 seconds per the facility hand hygiene procedure.
2. During observations of care on 9/14/21 at 10:20 AM at station 8, EI # 10, Certified Clinical Hemodialysis Technician (CCHT), disinfected the dialysis machine, removed gloves, and sanitized hands for 8 seconds before retrieving gloves from the clean glove supply. EI # 10 failed to follow the facility hand hygiene procedure.
3. During observations of care on 9/14/21 at 10:35 AM station 15 , EI # 4 removed the old CVC (central venous catheter) dressing, discarded the dressing, removed/discarded gloves and sanitized hands for 10 seconds and not at least 20 seconds per the facility hand hygiene procedure.
4. During observations of care on 9/14/21 at 10:46 AM at station 16, EI # 5, Patient Care Technician (PCT), removed needle 1 from the access site, removed/discarded gloves then sanitized hands for 8 seconds before retrieving gloves from the clean gloves supply. EI # 5 failed to sanitize hands per the facility hand hygiene procedure.

An interview was conducted on 9/16/21 at 8:45 AM and EI # 1, Clinic Manager, confirmed staff failed to follow the facility hand hygiene procedure.

5. An observation was conducted on 9/14/21 at 11:15 AM to observe EI # 8, CCHT, initiate dialysis on PI # 12. EI # 8 opened the treatment floor door and PI # 12 entered the treatment floor. PI # 12 weighed his/herself and proceeded to station 20 without performing hand hygiene as directed per the facility policy.
6. An observation was conducted on 9/14/21 at 11:50 AM to observe EI # 4 prepare and administer an IV medication (Heparin) to PI # 2 at station 19. EI # 4 failed to perform hand hygiene prior to accessing supplies and handling medication vials as directed per the facility policy.
7. An observation was conducted on 9/14/21 at 12:09 PM to observe EI # 9, RN, prepare and administer an IV medication (Venofer) to PI # 14 at station 8. EI # 9 failed to perform hand hygiene prior to accessing supplies and handling medication vials as directed per the facility policy.

An interview was conducted on 9/16/21 at 8:40 AM with EI # 1 who verified the staff failed to ensure the patient's performed hand hygiene when entering the treatment floor as per the facility policy. EI # 1 also verified the staff to perform hand hygiene before preparing IV medications as directed per the facility policy. 30952

V0122

IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL
CFR(s): 494.30(a)(4)(ii)

[The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

This STANDARD is not met as evidenced by:

Based on observations, facility policy, and interview, it was determined the facility failed to ensure staff cleaned and disinfected the dialysis station after patient treatments. This affected 2 of 2 observations of the cleaning and disinfection of the dialysis station and had the potential to affect all patients dialyzed by this facility. Findings include: Policy: Cleaning and Disinfection of the Dialysis Station Published: 11/02/2020 Version: 11 Purpose The purpose of this policy is to provide guidelines to prevent the spread of infectious disease in accordance with appropriate regulations, and to maintain a clean, safe, and aesthetically pleasant environment for patients, staff, and visitors. Responsibility All dialysis facility staff Dialysis Station Area including the dialysis machine, chair/bed and other reusable equipment... General Cleaning The dialysis station could become contaminated with blood and other body fluids during treatment... After use, all non-disposable equipment and supplies must be disinfected with 1:100 bleach or manufacturer's recommendation or discarded. Work Surface Cleaning and Disinfection without Visible Blood using Bleach Solutions. All work surfaces shall be cleaned and disinfected with 1:100 bleach solution after completion of procedures. Make the surface glistening wet and let air dry unless otherwise specified by the manufacturer. 1. An observation was conducted on 9/14/21 at 10:15 AM to observe Employee Identifier (EI) # 7, Registered Nurse (RN), perform cleaning and disinfection of dialysis station 27. While disinfecting the dialysis station, EI # 7 failed to clean and disinfect underneath the chairside table tops and the exterior chair panels bilaterally. An interview was conducted on 9/16/21 at 8:40 AM with EI # 1, Clinic Manager who verified the staff failed to clean and disinfect the dialysis station as directed per the facility policy. 30952 2. During observations of care on 9/14/21 at 10:20 AM at station 8, EI # 10, Certified Clinical Hemodialysis (HD) Technician disinfected the patient treatment chair, blood pressure (BP) cuff and tubing then placed the clean BP cuff/tubing equipment inside the wire basket on the HD machine. EI # 10 had not yet disinfected the HD machine and placed the clean BP equipment into a contaminated surface. EI # 10 then disinfected the HD machine but failed to disinfect the IV (intravenous) pole hooks. In an interview on 9/16/21 at 8:45 AM, EI # 1 confirmed staff failed to follow the facility dialysis station disinfection policy.

V0126

IC-HBV-VACCINATE PTS/STAFF
CFR(s): 494.30(a)(1)(i)

Hepatitis B Vaccination Vaccinate all susceptible patients and staff members against hepatitis B.

This STANDARD is not met as evidenced by:

Based on review of medical records (MR), facility policy, Hepatitis B Summary, and interview, it was determined the facility failed to ensure all patients were offered the hepatitis B vaccine series. This affected 1 of 1 new patient reviews, Patient Identifier

(PI) # 1 and had the potential to negatively affect all patients served by the facility. Findings include: Policy: Patient Testing and Vaccination for Hepatitis B Published: 08/20/2014 Version: 4 Hepatitis B (HB) Vaccine Guidelines: The Hepatitis B vaccine shall be offered to all susceptible patients... Patients shall sign a vaccination consent /declination form... A protective antibody response is 10 or more milliinternational units (mIU) per milliliter (anti-HBs > (greater than) 10mIU/mL). Hepatitis B Vaccine: Recombivax: Dialysis dependent for patients aged 20 or older = (equal) 40 ug (microgram) in 1.0 ml (milliliter) at 0, 1, and 6 months. Hepatitis B Vaccine: Engerix-B: Dialysis dependent for patients aged 20 or older = 40 ug in 2 - 1.0 mls at 0, 1, 2 and 6 months. Documentation in the patient's electronic MR system for administration as well as NON administrations is extremely important. These include: Refusals Allergic Vaccinated elsewhere... 1. PI # 1 was admitted to the facility on 3/15/18 with a primary diagnosis of End Stage Renal Disease. Review of the Hepatitis B Summary Report printed 9/14/21 revealed a hepatitis B surface antibody of < (less than) 10 on 7/29/21, susceptible. MR review on 9/15/21 revealed no patient consent, no vaccination record, and no declination/refusal for the Hepatitis B vaccination series, which was 53 days after admission to the facility. During an interview on 9/16/21 at 9:42 AM Employee Identifier # 1, Clinic Manager, confirmed staff failed to follow the facility policy for Hepatitis B vaccination.

V0130

IC-HBV-ISOLATION-MACHINES/EQUIP/SUPPLIES
CFR(s): 494.30(a)(1)(i)

Isolation of HBV+ Patients To isolate HBsAg positive patients, ... dedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV susceptible patients.

This STANDARD is not met as evidenced by:
Based on observations, review of facility policy and interview, it was determined the facility failed to ensure: 1. All equipment used in the isolation room was designated and labeled for "isolation" only. 2. Infectious Waste in the red bag was removed from the HBsAg (Hepatitis B surface Antigen) positive patient treatment isolation unit each day. This had the potential to negatively affect all Hepatitis B susceptible patients, visitors, and facility staff. Findings include: Facility Policy: Dialyzing Patients with Positive Hepatitis B Antigen Published: 3/20/13 Version: 7 Purpose: To prevent the transmission of Hepatitis B. Policy: ...all patients with hepatitis B infection treated in the dialysis facility require additional infection control precautions... Isolation of Hepatitis B virus positive (HBsAg+) patients. All patients who are HBsAg positive must dialyze under isolation precautions. Equipment and Supplies Separated dedicated supplies and equipment... must be used to provide care to the HBsAg positive patient. ...All supplies used in the isolation room/ area such as clamps, blood pressure cuffs, testing reagents, etc. (etcetera), should be labeled "isolation" and not routinely removed... All disposable items, including the patient's dialyzer, shall be considered infectious, and shall be red-bagged, labeled as Infectious Waste and removed from the HBsAg positive patient care room/area each day using Standard Precautions. 1. On 9/14/21 at 2:40 PM the surveyor toured the isolation room with Employee Identifier (EI) # 6, RN (Registered Nurse) Charge Nurse. The following items were in the isolation room and not labeled/dedicated for "isolation" use only: 3 Hemodialysis machines 4 patient treatment chairs 1 set of Tri-Station reagents for Myron L D-6 meter 1 biohazard waste container 1 privacy screen The biohazard container was not emptied following for the 9/13/21 isolation unit dialysis treatment and was 1/2 full of red-bagged hazardous waste. During the tour an interview was

conducted on 9/14/21 at 2:48 PM with EI # 6 who confirmed the equipment should have been designated labeled "isolation" and the red-bagged hazardous waste should have been emptied on 9/13/21.

V0143

IC-ASEPTIC TECHNIQUES FOR IV MEDS
CFR(s): 494.30(b)(2)

[The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and

This STANDARD is not met as evidenced by:
Based on observations, review of policy, and interviews, it was determined the facility failed to ensure staff: 1. Properly prepared medication for administration. 2. Stored medications as directed per the facility policy. This did affect Patient Identifier (PI) # 15, PI # 14 (which was 1 of 3 Intravenous {IV} medication observations) and 2 unsampled patient and had the potential to negatively affect all patients served by this facility. Findings include: Facility Policy: Medication Preparation and Administration Published: 04/05/2021 Version: 6 "Purpose: To administer medications with the goals of staff and patient safety, optimal therapeutic response, and infection control. Pre-drawing Medications Medications may be pre-drawn up to 4 hours... These pre-drawn medications shall be labeled and must be kept under the preparer's control or in a locked designated medication storage area ... until delivery to the appropriate patient for administration. Infection Control ...Aseptic technique will be used to prepare and administer IV medications. ...Cleanse the diaphragm of a vial with alcohol prior to accessing the vial. 1. During observations on the treatment floor on 9/14/21 at 9:25 AM at station 15, the surveyor observed 2 syringes labeled "Heparin" lying on the chairside tabletop of PI # 15. At 9:35 AM, the Registered Nurse (RN) entered the dialysis station. The staff failed to keep the Heparin under the preparer's control or in a locked designated medication storage area until delivery to the patient station for administration as per the facility policy. An interview was conducted on 9/16/21 at 8:45 AM with Employee Identifier (EI) # 1, Clinic Manager, who confirmed staff failed to properly prepare and store medications as directed per the facility policy. 2. During observations on the treatment floor on 9/14/21 at 9:30 AM the surveyor observed 2 syringes labeled "Heparin" lying on the chairside tabletop of an unsampled patient at station 22. The medications were left unattended and the staff failed to ensure medications were kept under their control as directed per the facility policy. 3. During observations on the treatment floor on 9/14/21 at 10:07 AM the surveyor observed 2 syringes labeled "Heparin" lying on the chairside tabletop of an unsampled patient at station 8. The medications were left unattended and the staff failed to ensure medications were kept under their control as directed per the facility policy. 4. An observation was conducted on 9/14/21 at 12:09 PM to observe EI # 9, RN, prepare and administer an IV medication (Venofer) to PI # 14 at station 8. EI # 9 opened 1 vial of Venofer and proceeded to withdraw the medication into the syringe without first cleaning the diaphragm (stopper) as directed per the facility policy. An interview was conducted on 9/16/21 at 8:40 AM with EI # 1 who verified the staff failed to properly prepare and store medications as directed per the facility policy. 30952

V0250

DIALYS PROPORT-MONITOR PH/CONDUCTIVITY
CFR(s): 494.40(a)

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.

This STANDARD is not met as evidenced by:

Based on observations, facility policy, Digital Dialysate Meter Operation Manual, and interview, it was determined the staff failed to: 1. Follow Instructions for Use (IFU) Myron L D6 Meter, facility policy and procedures for monitoring dialysate conductivity prior to treatment initiation. 2. Follow the facility policy and test the dialysate pH (the acidity or alkalinity of a substance) when a bath acid concentration was changed which affected Patient Identifier (PI) # 18, an unsampled patient. This affected 3 of 3 observations made and had the potential to negatively affect all patients who dialyze at this facility. Findings include: Facility Policy: Checking Conductivity and pH of Final Dialysate Published: 08/03/2020 Version: 7 Purpose: The purpose of this policy is to provide guidelines to verify final dialysate conductivity and pH prior to initiating hemodialysis treatments ... Test Verification Prior to Treatment Incenter setting: 2 staff members will verify the conductivity and pH parameters prior to treatment ... Policy ...Dialysate pH must be tested when changing acid concentrate formulations (example 1 K (Potassium) to 2 K during the treatment.... Facility Procedure: Myron L D6 Measuring Procedures Version: 1 Published: 06/14/2017 Measuring Dialysate Conductivity and pH 7. Return sample to cart or sampling area and perform measurements according to the D6 meter's IFU (Instructions for use). Digital Dialysate Meter Operation Manual Myron L D-6 Meter 02/16/2018 VII. Specific Recommended Measuring Procedures Page 12 CAUTION: For Cond/Res/TDS (Conductivity/Resistivity/Total Dissolved Solids) Measurements: - The pH/ORP (Oxidation Reduction Potential) sensor well cap MUST be sealed. - Any crystals or other residue around the cap MUST be rinsed away to prevent contamination of the conductivity sample. - The conductivity cell MUST be rinsed and filled at least 3 times with sample before each measurement is taken. For pH/ORP measurements: - Both the pH/ORP sensor well and the conductivity cell must be rinsed and filled at least 3 times with sample before each measurement is taken ... A. Measuring Conductivity & Total Dissolved Solids ... 1. Rinse cell cup 3 times with sample to be measured. 2. Refill cell cup with sample. 3. Press COND or TDS button. 4. Take reading ... C. Measuring pH (D-6) 1. Remove protective cap ... 2. Rinse pH /ORP sensor well and conductivity cell 3 times with sample to be measured. Shake out each sample to remove any residual liquid. 3. Refill pH/ORP sensor well and conductivity cell with sample. 4. Press pH button. 5. Note value displayed. 6. Important: After use, fill pH/ORP sensor well with Myron L pH Sensor Storage Solution and replace protective cap ... Never use distilled water or plain tap water ... 1. During observations of care on 9/14/21 at 9:45 AM, the surveyor observed EI (Employee Identifier) # 5, PCT, (Patient Care Technician) perform dialysate conductivity and pH testing using a Myron L D-6 meter. EI # 5 filled a cup with dialysate and proceeded to the test station "dirty sink" area. EI # 5 filled the D-6 meter conductivity cell and sensor well with a dialysate sample 1 time, then obtained the conductivity and pH reading confirmed by EI # 4, Registered Nurse, who was present during conductivity and pH test. EI # 5 discarded the dialysate solution in the dirty sink, placed the D 6-meter on the sink counter then exited the test station. EI # 5 failed to rinse the residue from the meter. EI # 5 failed to follow the manufacturer's instructions for use for dialysate testing, rinse and fill the conductivity cell at least 3 times with sample before each measurement was taken, then refill cell cup with the dialysate sample and obtain the reading. 2. On 9/14/21 at 10:00 AM at station 19, EI # 5, PCT initiated dialysis treatment for a 2 K 2.5 Ca (calcium) bath. At 10:37 AM, EI #

5 placed a jug bath labeled 3 K 2.5 Ca at the base of the HD (hemodialysis) machine at station 19 for PI # 18. The surveyor asked EI # 5 why the dialysis bath was changed? EI # 5 stated, "I just looked at the orders and this is the bath ordered". EI # 5 failed to test the dialysate pH when the dialysis bath acid concentrate was changed from 2 K to 3 K. In an interview on 9/16/21 at 8:45 AM, EI # 1, Clinic Manager confirmed staff failed to follow facility policy and check conductivity and pH of final dialysate when the acid concentrate was changed. 3. At 11:17 AM the surveyor observed EI # 5, perform dialysate conductivity and pH testing using a Myron L D6 meter at the "dirty sink" area. EI # 5 filled the conductivity cell and sensor well of the D6 meter with a dialysate sample 1 time and obtained the readings for conductivity and pH. EI # 5 then emptied the solution in the dirty sink placed the D6 meter on the sink without rinsing the D6 meter Reverse Osmosis (RO) water. EI # 5 failed to follow the manufacturer's instructions for use for dialysate testing, rinse and fill the conductivity cell at least 3 times with sample before each measurement was taken, then refill cell cup with the dialysate sample and obtain the reading. 4. At 11:18 AM the surveyor observed EI # 8, CCHT (Certified Clinical Hemodialysis Technician), perform dialysate conductivity and pH testing using a Myron L D6 meter at the dirty sink area. EI # 8 filled the conductivity cell and sensor well of the D6 meter with a dialysate sample 1 time and obtained the readings for conductivity and pH. EI # 8 then emptied the solution in the dirty sink placed the D6 meter on the sink without rinsing the D6 meter RO water. EI # 8 failed to follow the manufacturer's instructions for use for dialysate testing, rinse and fill the conductivity cell at least 3 times with sample before each measurement was taken, then refill cell cup with the dialysate sample and obtain the reading. A telephone interview was conducted on 9/17/21 at 10:55 AM with EI # 1, Clinic Manager who verified the staff failed to follow the IFU Myron L D6 Meter. 30952

V0452

PR-RESPECT & DIGNITY
CFR(s): 494.70(a)(1)

The patient has the right to- (1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD

This STANDARD is not met as evidenced by:
Based on review of the medical record (MR), facility policy, and interviews with the staff it was determined the facility failed to ensure the staff treated the patient with respect and dignity. This affected 1 of 3 MR's reviewed and did affect Patient Identifier (PI) #1 and had the potential to negatively affect all patients served by the facility. Findings include: Facility Policy: Patient Rights and Responsibilities No Policy Number Published: 4/4/12 Version: 2 Purpose: To comply with Federal Regulations that require dialysis facilities to: Educate staff regarding the rights of dialysis patients. Inform and educate all dialysis patients about their rights and responsibilities as a patient at the dialysis facility. Ensure patient's rights are respected and protected by the facility. Conditions for Coverage: Patients' Rights: ...Patients' Rights require dialysis facilities to inform patients or their representatives of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights. The patient has the right to: 1. Respect, dignity and recognition of his or hers individuality and personal needs... 5. Be informed about and participate if desired, in all aspects of his or her care, and be informed of the right to refuse treatment and to discontinue treatment... Policy: All patients and/or their representatives will be informed of their

rights (including privacy rights) and responsibilities. Patient rights and the ability to exercise these rights must be protected by the facility. FMCNA (Fresenius Medical Care North America) Patient Rights Form You Have The Right To: Care that is Respectful: Be protected from discrimination and harassment... Be treated with dignity, consideration, respect and full recognition of your individuality and personal needs... Help Make Decisions About Your Care: Accept, refuse or stop any treatment that is prescribed for you. PI # 1 was admitted to the facility on 5/12/18 with an admitting diagnosis of End Stage Renal Disease. Review of the Treatment Sheet dated 5/13/21 revealed documentation by the RN (Registered Nurse), "Pt (patient) very belligerent during Dr. (doctor) visit. Patient demanded the he/she didn't see physician. Pt had covers over head entire TX (treatment)". Review of the physician rounding note dated 5/13/21 revealed Employee Identifier (EI) # 6, Medical Doctor, documented pt belligerent and agitated, refused exam, yelling and cursing with the team present. Explained that she was a provider with the practice and was assuming care with the practice. Review of the Provider Rounding Note dated 5/18/21 revealed EI # 7, Nurse Practitioner (NP), documented PI # 1 more reasonable demeanor today than last week. Patient continues to express that he/she does not want to be seen by EI # 6. Review of the MR revealed a letter dated 5/20/21 to PI # 1 from the Doctors of Renal Associates stating they will no longer be able to serve as your doctors effective 6/20/21 due to behavior toward staff. Review of the Treatment Flow Sheets dated 6/8/21 to 7/6/21 revealed no documentation by the staff concerning the patient's behavior nor was there documentation of PI # 1 having the covers over his/her head during the treatments. Review of the MR revealed a letter dated 6/22/21 with an original date of 6/16/21 which had been crossed through and re-dated with 6/22/21 stating Notice of Discharge and signed by EI # 2, Clinic Manager, and EI # 5, Medical Director. The letter stated Fresenius Kidney Care, Capital City will no longer be able to provide medical care or dialysis treatments to PI # 1 effective 7/22/21 with original date of 7/16/21 which had been crossed through and re-dated 7/22/21. Review of the Physician Order Sheet dated 6/22/21 revealed the following order: Involuntary discharge due to no Physician effective date 7/22/21. Review of the Involuntary Discharge (IVD) Patient Review Worksheet dated 7/3/21 revealed a potential discharge date of 7/16/21 revealed a summary stating due to past incidents of what Pt felt was disrespect made toward him by Dr. (Name), he has expressed that he does not want him/her to provide him with care. Since that time, Pt has avoided the doctor by shortening his/her treatments when he/she was rounding in the clinic. On 5/13/21, Pt was asleep during MD rounds and MD shook patient to wake him in order to discuss his labs. This angered the Pt, who began yelling at the MD. MD informed Renal Associates of Montgomery, with whom he/she was employed, of the incident. Renal Associates of Montgomery made the decision to discharge Pt from their services. Clinic was not made aware of discharge until Pt informed staff that he/she received a termination letter from Renal Associates of Montgomery. Further review of the IVD revealed the signatures of the Medical Director, Social Worker and Dietitian and documented below the signatures dated 7/3/21 was written by hand transferred to a non-FKC (Fresenius Kidney Care) facility and signed per the Clinic Manager. Review of the Patient Discharge Assessment dated 7/8/21 revealed under remarks patient informed by Director of Operations that involuntary discharge was being withdrawn. Patient elected to transfer to non-FMC (Fresenius Medical Care) clinic. Review of the Clinical Note Report dated 7/8/21 revealed documentation the patient was discharged to another dialysis facility. RD (Registered Dietitian) will no longer follow. An interview was conducted on 9/14/21 at 3:30 PM with PI # 1 who stated EI # 6, Medical Doctor, "has an ego or something. I cover my face with the blanket all the time and all the time the staff tells me to uncover it. One day (PI # 1 was asked the date but was not sure), (EI # 6) came up and ripped the covers off and I had a cap on

my head which fell to the floor". PI # 1 said something to the physician and he/she introduced his/herself and PI # 1 asked if he/she was going to say he/she was sorry or pick up his hat. PI # 1 stated he/she started yelling, "Help Help", because he/she would not leave when PI # 1 asked him/her too. "I signed off early three times after that because the physician is overbearing and rude". The patient went on to state that again this year the physician made rounds and the patient was asleep with the covers over his head. The patient stated he/she felt someone between his/her chair and the dialysis machine and thought it was a technician (tech). The patient stated then he/she heard someone barking at him/her about the covers and then felt someone bump his/her arm. PI # 1 stated he/she pulled the covers down and the physician was yelling at him/her about the covers, The patient stated the Social Worker, the Dietitian and the Nurse Practitioner (NP) were also there but a ways away from the chair. The patient stated he/she said hi to the NP and the NP replied "Oh don't get me involved." PI # 1 stated he/she asked the physician to leave and he/she stated he cursed at the physician and asked her/him again to leave and the physician stated "that's all I needed." That was the end of that, then I was discharged. The patient stated "he/she would always disrespect me and I don't know why." The patient stated he/she would always sign off early so the patient did not have to deal with the physician but this time the patient was asleep so the patient not see the physician coming. An interview was conducted on 9/15/21 at 8:50 AM with EI # 2, Clinical Manager. When asked if EI # 2 recalled PI # 1 he/she stated yes that some days PI # 1 was calm and nice but other days would just fly off the handle. When asked what caused the conflict between the patient and the physician, EI # 2 stated the patient would have the covers over his/her head the physician would come and pull the covers off and the patient would be startled. The physician told the patient he/she was making rounds and there to do the patient's assessment. The patient then said "No I do not want you touching me." When EI # 2 was asked when the last incident occurred EI # 2 stated "my best guess would be it occurred on 6/17/21." EI # 2 was asked what occurred on 6/17/21. EI # 2 stated they went to the patient's station to review the patient's labs and the physician woke him up by I think shaking him and maybe calling his name. The patient removed the covers and said "I don't want you any where near me. The physician said that was fine but he/she was going to review the labs with him and if he did not want him/her to assess him that was fine also and the physician started reviewing the lab work. The patient then got loud and said " your a rapist and you are raping me" EI # 2 was asked how the patient got discharged and not involuntarily discharged. EI # 2 stated the Medical Director stopped the Involuntary Discharge and the patient could stay and EI # 1, Director of Operations, talked to the patient and explained this to him/her. The patient then asked what guarantee this will not happen again and he was told there was no guarantee so the patient asked to be transferred. An interview was conducted on 9/15/21 at 9:00 AM with EI # 3, Registered Dietitian. During the interview EI # 3 was asked if he/she remembered the incident which took place between the physician and PI # 1 and he/she stated yes. EI # 3 was asked to explain what took place that day during rounds with the physician. EI # 3 stated PI # 1's section was the last section to round on. EI # 3 stated the patient usually signs off early when the physician is making rounds so there must be something that happened prior to this incident. EI # 3 stated patient had the covers over his/her head and was asleep. EI # 3 stated the physician approached the patient's chair and he/she always wakes the patient up. EI # 3 was unsure how the physician woke the patient up this time. Once the patient pulled the covers down and saw it was the physician the patient said over and over "I do not want to talk to you." The physician told the patient they needed to review his/her labs and started reading the lab results to the patient. EI # 3 then stated the patient said "I keep telling you I don't want to talk to you but you won't leave. I'm saying no, you must be a rapist because you won't stop you are raping me." An interview was

conducted on 9/15/21 at 9:50 AM with EI # 4, Social Worker. EI # 4 was asked if he /she remembered the incident which occurred between the patient and the physician. He/she stated yes and explained. EI # 4 stated they were making round with the physician and the patient had the covers over his/her head and did not know they were on the dialysis floor. EI # 4 stated physician removed the covers from patient's head and patient became irate. The patient immediately said "Oh man bitch I told you to leave me alone" He continued by stating he/she told the physician he/she did not want to talk to him/her at all and he/she was fine till he/she (EI #6) showed up. The physician stayed there and finished rounds with the patient even though the patient kept on and on telling the physician to leave. The physician finally walked away and physician said the patient was being immature. Upon the completion of the interview with EI # 4, this surveyor asked if EI # 4 had documented the incident. EI # 4 replied with a yes and a copy of the documentation was requested. EI # 4 approached the surveyor after looking for the documentation and no documentation could be found in the MR. An interview was conducted on 9/15/21 at 10:42 AM with EI # 1, Director of Operations. EI # 1 reported an incident occurred sometime in June with the patient and EI # 6. "I was in the clinic that day and the patient told me that (he/she) informed the staff if PI # 6 arrived at the clinic the staff was to tell (him/her) so (he/she) could leave the clinic. I went over to (his/her) chair and was going to wake the patient up because the physician arrived at the clinic. I was told by the staff if you wake the patient up he/she will leave. I decided not to wake the patient up". EI # 1 stated when he/she went out the the floor the whole team was surrounding the patient at chairside. The patient was saying I told you not to touch me and I don't want you to talk to me and then he/she started yelling and screaming and calling her/him (EI # 6) a rapist. When the doctor walked off the floor she/he asked EI # 1 to come back there where he /she was and stated "something needs to be done." I then went out to the floor to speak with the patient and he/she calmed down but did leave the clinic. When the physician came back on second shift for rounds he/she said he/she wants the patient fired from their services. I said FMC was not discharging the patient and that we would get another group to pick the patient up. At that time the physician did not like that. EI # 1 stated he/she received a call from the Medical Director who stated Network was contacted and the involuntary discharge was discussed. EI # 1 stated "much later" (time undetermined) he/she received another call from the Medical Director stating the discharge was to be canceled and to notify the patient of the cancellation of the discharge. During this interview with EI # 1 the surveyor asked if EI # 1 had documentation of the incident in the MR. EI # 1 stated he/she did. On 9/15/21 at 11:30 EI # 1 was asked for his/her documentation on the incident and responded by stating he/she knows it was documented but can not find it in the computer system but will keep searching. At the conclusion of the day prior to leaving the facility the surveyor again asked for the documentation and none was provided. An interview was conducted on 9/15/21 at 12:10 PM with EI # 5, Medical Director, by phone and was asked if EI # 5 recalled an incident which occurred on the dialysis floor with PI # 1. EI # 5 stated he/she recalled being told about the incident but was not present. EI # 5 stated the physician which was rounding had some issues with the patient several months ago but no other associates witnessed this incident. After this incident with the patient the physician (EI # 6) came to the group and demanded PI # 1 be discharged. At that time this physician did not see the patient anymore. EI # 5 was asked if the patient was involuntarily discharged and EI # 5 stated they (associate group) initiated the involuntary discharge and EI # 5 signed it and a letter had been sent to the patient. EI # 5 stated he/she received a call from Network 8 who discussed with him concerns about the involuntary discharge and the letter. EI # 5 stated we decided at that time we did not need to disrupt things. EI # 5 stated about a week later the area manager informed him/her the patient had been accepted to another facility. An interview was

conducted on 9/15/21 at 2:25 PM with EI # 6, Medical Doctor. EI # 6 was asked if he/she recalled PI # 1 and stated the physician had only met the patient 2-3 times so probably could not describe the patient very well. EI # 6 was asked to describe what had recently occurred with the patient. EI # 6 stated the most recent incident occurred when they made rounds. EI # 6 was asked when this occurred and EI # 6 continued to state what happened. EI # 6 stated he/she had awoken the patient and the patient became instantly angry. He/she spoke some obscenities and told me to keep moving. EI # 6 stated he/she told the patient they were going to go over some lab work and the patient stated the physician will not be his/her physician. EI # 6 stated he/she told the patient they were a team of 6 and were to provide him/her with care and he/she will be seen by any one of the 6 providers. EI # 6 then stated the patient was told EI # 6 was reviewing the labs with the team and the patient became louder and started calling the physician a rapist. EI # 6 stated they as a team did review his/her labs. EI # 6 stated after the incident the associate group all met and he/she discussed the patient's behavior with the group and as far as he/she knew a letter was sent to the patient to discharge him/her from the associate group and as far as he/she knew the patient went to another dialysis center.

V0456

PR-PARTICIPATE IN CARE;DISC/REFUSE TX
CFR(s): 494.70(a)(5)

The patient has the right to- (5) Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research;

This STANDARD is not met as evidenced by:
Based on review of medical records (MR), facility policy, and interviews with the staff it was determined the facility failed to ensure the patient had the right to refuse treatment and the staff complied with this right. This affected 1 of 3 MR reviewed and did affect Patient Identifier (PI) # 1 and had the potential to negatively affect all patients served by the facility. Findings include: Facility Policy: Patient Rights and Responsibilities No Policy Number Published: 4/4/12 Version: 2 Purpose: To comply with Federal Regulations that require dialysis facilities to: Educate staff regarding the rights of dialysis patients. Inform and educate all dialysis patients about their rights and responsibilities as a patient at the dialysis facility. Ensure patient's rights are respected and protected by the facility. Conditions for Coverage: Patients' Rights: ... Patients' Rights require dialysis facilities to inform patients or their representatives of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights. The patient has the right to: 5. Be informed about and participate if desired, in all aspects of his or her care, and be informed of the right to refuse treatment and to discontinue treatment... Policy: All patients and/or their representatives will be informed of their rights (including privacy rights) and responsibilities. Patient rights and the ability to exercise these rights must be protected by the facility. FMCNA (Fresenius Medical Care North America) Patient Rights You Have The Right To: Help Make Decisions About Your Care: Accept, refuse or stop any treatment that is prescribed for you. PI # 1 was admitted to the facility on 5/12/18 with an admitting diagnosis of End Stage Renal Disease. Review of the Treatment Sheet dated 5/13/21 revealed documentation by the RN (Registered Nurse), "Pt (patient) very belligerent during Dr. (doctor) visit. Patient demanded the (he/she) didn't see physician. Pt had covers over head entire TX (treatment)". Review of the physician rounding note dated 5/13/21 revealed Employee Identifier (EI) # 6 documented, 'Pt belligerent and agitated, refused exam, yelling and

cursing with the team present. Explained that I am a provider with the practice and assuming care with the practice". Review of the Provider Rounding Note dated 5/18/21 revealed EI # 7 Nurse Practitioner (NP) documented PI # 1 more reasonable demeanor today than last week. Patient continues to express that he/she does not want to be seen by EI # 6, Medical Doctor (MD) and did not want EI # 6 touching him. Review of the Treatment Flow Sheets dated 6/8/21 to 7/6/21 revealed no documentation by the staff concerning of any incident which occurred on the treatment floor with the physician and the patient. An interview was conducted on 9/14/21 at 3:30 PM with PI # 1, who stated. "I cover my face with the blanket all the time and all the time the staff tells me to uncover it. One day (PI # 1 was asked the date but was not sure), EI # 6 came up and ripped the covers off of me and I had a cap on my head which fell to the floor. I said something to (him/her) and (he/she) introduced (his/herself) and I asked if (he/she) was going to say (he/she) was sorry or pick up my hat. I started yelling Help Help because (he/she) would not leave when I asked (him/her) too. I signed off early three times after that because (he/she) is overbearing and rude". The patient went on to state that again this year EI # 6 made rounds and he/she was asleep with the covers over his/her head. The patient stated he/she felt someone between his/her chair and the dialysis machine and thought it was a technician (tech). PI # 1 stated then he/she heard someone barking at him/her about the covers and then felt someone bump his/her arm. PI # 1 stated he/she pulled the covers down and EI # 6 was yelling at him/her about the covers, PI # 1 stated the Social Worker, the Dietitian and the Nurse Practitioner (NP) were also there but a ways away from the chair. PI # 1 stated he/she said hi to the NP and the NP replied "Oh don't get me involved." Patient then stated he/she asked the physician to leave and he/she stated he/she cussed at the physician and asked the physician again to leave and the physician stated "that's all I needed". He/she would always disrespect me and I don't know why. PI # 1 stated I would always sign off early so I did not have to deal with that physician but this time I was asleep so I did not see him/her coming. An interview was conducted on 9/15/21 at 8:50 AM with EI # 2, Clinical Manager. When asked what caused the conflict between the patient and the physician, EI # 2 stated it started a few months ago when the patient would have the covers over his/her head the physician would come and pull the covers off and the patient would be startled. EI # 2 stated the last occurrence was around June 17th when the physician pulled the covers off the patient's head on this day and told the patient they were going to discuss his/her lab work and do his/her assessment. The patient then stated "No I do not want you anywhere near me". EI # 2 stated the physician remained at chairside and reviewed the labs with the patient while the whole time the patient was telling the physician he/she did not want him/her to touch the patient and to leave. An interview was conducted on 9/15/21 at 9:00 AM with EI # 3, Registered Dietitian. EI # 3 was asked to explain the incident between the patient and the physician. EI # 3 stated patient had the covers over his/her head and was asleep. EI # 3 stated the physician approached the patient's chair and he/she always wakes the patient up. EI # 3 was unsure how the physician woke the patient up this time. Once the patient pulled the covers down and saw it was the physician the patient said over and over "I do not want to talk to you." The physician told the patient they needed to review his/her labs and started reading the lab results to the patient. EI # 3 then stated the patient said "I keep telling you I don't want to talk to you but you won't leave. I'm saying no". An interview was conducted on 9/15/21 at 9:50 AM with EI # 4, Social Worker. EI # 4 stated they were making round with the physician and the patient had the covers over his/her head and did not know they were on the dialysis floor. EI # 4 stated physician removed the covers from patient's head and patient became irate. The patient immediately said "Oh man I told you to leave me alone" He/she continued by stating he/she told the physician he/she did not want to talk to him/her at all and he/she was fine till he/she

showed up. The physician stayed there and finished rounds with the patient even though the patient kept on and on telling the physician to leave. The physician finally walked away and physician said the patient was being immature. An interview was conducted on 9/15/21 at 10:42 AM with EI # 1, Director of Operations. EI # 1 reported an incident occurred sometime in June with the patient and the physician. EI # 1 stated he/she,"was in the clinic that day and the patient told me that he/she informed the staff if the physician arrived at the clinic the staff was to tell him/her so he/she could leave the clinic. I went over to his/her chair and was going to wake the patient up because the physician arrived at the clinic. I was told by the staff if you wake the patient up he/she will leave early. I decided not to wake the patient up". EI # 1 stated when he/she went out the the floor the whole team was surrounding the patient at chairside. The patient was saying I told you not to touch me and I don't want you to talk to me and then he/she started yelling and screaming and calling her/him a rapist. An interview was conducted on 9/15/21 at 12:10 PM with EI # 5, Medical Director, by phone and was asked if EI # 5 recalled an incident which occurred on the dialysis floor with PI # 1. EI # 5 stated he/she recalled being told about the incident but was not present. After this incident with the patient the physician (EI # 6) came to the group and demanded PI # 1 be discharged. At that time this physician did not see the patient anymore. At his/her request and, she/he was very forceful, we were forced by him/her and it was decided it was best for the patient to go to another group or clinic. An interview was conducted on 9/15/21 at 2:25 PM with EI # 6, Medical Doctor. EI # 6 was asked if he/she recalled PI # 1 and stated the physician had only met the patient 2-3 times so probably could not describe the patient very well. EI # 6 stated,"(he/she) had awoken the patient and the patient became instantly angry. (He /she) spoke some obscenities and told me to keep moving". EI # 6 stated," I told the patient we were going to go over some lab work" and the patient stated the physician will not be his/her physician. The physician told the patient they were a team of 6 and were to provide him/her with care and he/she will be seen by any one of the 6 providers. EI # 6 then told the patient he/she was reviewing the labs and the patient became louder and started calling the physician a rapist. EI # 6 stated they as a team did review his/her labs and once complete he/she left the chairside.

V0540

CFC-PATIENT PLAN OF CARE
CFR(s): 494.90

This CONDITION is not met as evidenced by:
Based on review of medical records (MR), facility policies and interviews, it was determined the facility failed to ensure staff provided care according to facility policies and procedures, physician orders and the patient's Plan of Care (POC) during care delivery. This had the potential to negatively affect all patients who dialyzed at this facility. Refer to: V 542, V 543, V 544, V 545, V 550 and V 551.

V0542

POC-IDT DEVELOPS PLAN OF CARE
CFR(s): 494.90(a)

The interdisciplinary team must develop a plan of care for each patient.

This STANDARD is not met as evidenced by:
Based on the review of medical records (MR), facility policy and interview, it was determined the facility failed to ensure the interdisciplinary team developed the

patients' plan of care in 2 of 2 records reviewed for admissions to the facility within the last 30 days and the last 90 days. This affected Patient Identifier's (PI) # 1 and PI # 3 had the potential to negatively affect all patients served by this facility. Findings Include: Facility Policy: Comprehensive Interdisciplinary Assessment and Plan of Care Published: 04/24/2019 Version: 5 ...The Comprehensive Interdisciplinary Assessment (CIA) and Plan of Care (POC) must be developed and implemented by an interdisciplinary team (IDT) consisting of at a minimum, the patient or patient's designee (if patient desires), a registered nurse, the patient's attending physician (and physician extender where allowed by State regulations), qualified social worker and qualified registered dietitian. The CIA and POC and for New Patients must be completed electronically in the patient's MR. The POC must be signed at the time of the IDT meeting for those attending in person or if remotely attending within 30 days of the IDT meeting... CIA and POC for New Patients to Dialysis ...Implementation of monthly or annual updates of the POC must be performed within 25 days of completion... A follow up CIA must occur within 90 days. The POC should be adjusted as appropriate and implemented within 15 days of reassessment. 1. PI # 1 was admitted to the facility 7/24/21 with diagnoses including End Stage Renal Disease (ESRD). MR review revealed the IDT POC Meeting date was 8/26/21. There was no reason for the meeting documented, no list of attendees and no signature of any IDT members. An interview was conducted on 9/16/21 at 9:02 AM with Employee Identifier (EI) # 1, Clinic Manager, who confirmed there was no documentation of the IDT team members who attended the 8/26/21 New Patient POC meeting and no date the POC was approved/implemented by the IDT. 2. PI # 3 was admitted to the facility 6/3/21 with diagnoses including ESRD. MR review revealed the IDT POC Meeting date was 8/26/21. There was no reason for the meeting documented, no list of attendees and no signature of any IDT members. An interview was conducted on 9/16/21 at 9:42 AM with EI # 1, who confirmed there was no documentation of the IDT team members who attended the 8/26/21 POC 90 Day Follow up meeting and no date the POC was approved/implemented by the IDT.

V0543

POC-MANAGE VOLUME STATUS
CFR(s): 494.90(a)(1)

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;

This STANDARD is not met as evidenced by:

Based on observations, review of the medical records (MR), facility policies, and interviews, it was determined the facility staff failed to ensure: 1. Patient faces, and access sites were visible and uncovered. 2. Changes in the patient condition which included BP (blood pressure) were reported to the nurse. 3. The Uncontrolled Hypertension algorithm was followed, BP's were re-checked, Clonidine was administered, and BP medication(s) reviewed for compliance/needs. 4. Blood pressure and pulse rate every 30 minutes were monitored or more as needed but not to exceed 45 minutes. 5. The physician was notified when physician's orders for the patient's Estimated Dry Weight (EDW) at the end of each treatment was not achieved. 6. The amount of normal saline used for prime was performed and documented. This affected 3 unsampled patients observed during observations of care, and 6 of 10 records reviewed including PI (Patient Identifier) # 5, PI # 7, PI # 3, PI # 1, PI # 4, and PI # 10. This had the potential to negatively affect all patients who dialyzed at the facility. Findings include: Facility Policy: Patient Assessment and Monitoring Published Date:

09/29/18 Version: 3 Pre-Treatment: Direct patient care staff may collect pre-treatment weight, BP (blood pressure), pulse, respirations, temperature, general observation, access, and complaints reported by the patient. ...An abnormal finding confirmed by the RN (Registered Nurse) will be reported to the attending physician for assessment and intervention. During Treatment: The RN will assess/ re-assess any findings addressed pre or during treatment as needed. Post-Treatment Non-licensed staff may collect post-treatment weight, BP, pulse...general observations... complaints reported by the patient. The staff member who evaluates the information and evaluates the patient post-treatment will document their findings on the...record. If any changes or abnormal findings...are observed or reported...the PCT (Patient Care Technician)... must report the changes in the patient condition to a RN who will further assess the patient prior to discharge after treatment. An abnormal finding confirmed by the RN will be reported to the attending physician if necessary...for assessment and intervention. The RN will assess/re-assess any findings addressed pre-treatment prior to discharge. Follow steps...obtaining pre-treatment assessment data: Step 1 The direct care staff may obtain the following data: weight... record pre-weight. Compare pre-weight to EDW. Step 2 During nursing rounds, the RN will review the data...and assess the following parameters as needed: ...Assess patient for symptoms... Step 3 Document findings and interventions in the medical record. Contact the physician as needed for additional orders based on assessment findings and clinical judgement. Monitoring During Treatment Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes...Document machine parameter and safety checks every 30 minutes or more often as needed but not to exceed 45 minutes... Follow the steps below for monitoring patient and machine parameters during treatment: Step 1. BP...Recheck BP after a drop that requires intervention such as administering normal saline... Report to the nurse: Systolic BPs > (greater than) 180 mm/Hg (millimeter/mercury) Diastolic BP > 100 mm/Hg BP less than or equal to 100 mm/hg systolic... ...Ultrafiltration (UF) Rate: Monitor UF rate. Note: UF rates greater than 13 ml/kg/hr (milliliters/kilogram/hour) should be avoided if possible by providing adequate prescribed dialysis duration, and scheduling of additional treatments... ...General Observations/Mental StatusAll patients must be under visual observation by clinical staff during treatment...Ensure each patient's face is visible and uncovered... Access Observe connections are secure and visible...Ensure access remains uncovered throughout the treatment...Observe and ensure....needles are intact... 4. Document any findings and interventions in the medical record. Facility In-Center HD (Hemodialysis) Standing Orders Uncontrolled Hypertension (elevated BP) algorithm: Notify MD (Medical Doctor)...for BP greater than equal to 180 systolic or diastolic greater than equal to 110 one hour or more into...treatment... Verify...not allergic to...clonidine then... 1...repeat BP...2. If BP remains at or above 180 systolic or 110 diastolic then, 3. Determine current BP meds (medications) patient is taking... 4...if any BP medications...need...refilled 5. Administer clonidine 0.2 mg (milligram) PO (by mouth)...8. Notify MD...if 60 minutes post clonidine BP....above 180/110 for additional recommendations. 1. During observations of care on 9/14/21, the surveyor observed the following: At 9:25 AM at station 5, the unsampled patient access was covered with a blanket. At 9:26 AM at station 16, the unsampled patient face and access were covered with a blanket. At 9:40 AM at station 1, the unsampled patient access was covered with a blanket. At 9:55 AM at station 5, the unsampled patient access remained covered. At 10:10 AM at station 16, the unsampled patient access remained covered. At 10:36 AM, at station 16, the unsampled patient access remained covered. 2. PI # 5 was admitted to the facility on 7/3/19 with diagnoses including Diabetes Mellitus with Diabetic Nephropathy and ESRD (End Stage Renal Disease). MR review revealed physician In-Center HD Standing Orders dated 12/16/2020 which included the above Uncontrolled Hypertension algorithm. Review of the

Treatment Sheet dated 9/1/21 revealed the RN documented a pre treatment BP 210/89 at 6:03 AM and at treatment start 6:21 AM, the BP was 180/91, (patient) denies complaints. Further review of the 9/1/21 Treatment Sheet revealed the following PCT (Patient Care Technician) documentation: At 6:34 AM, BP 203/103, denies complaints At 7:00 AM, BP 206/114, denies complaints At 7:30 AM, BP 221/112, denies complaints At 8:03 AM, BP 197/114 There was no documentation the PCT notified the RN the BP's were above 180 systolic and above diastolic 110 one hour into treatment. There was no documentation Clonidine was administered and current BP med compliance/needs were evaluated/verified. Review of the Treatment Sheet dated 9/8/21 revealed the RN documented a pre treatment BP 203/109 at 5:59 AM and at treatment start 6:11 AM the BP was 180/102, denies complaints. Further review of the 9/8/21 Treatment Sheet revealed the following PCT documentation: At 6:32 AM, BP 203/103, denies complaints At 7:02 AM BP 203/104, denies complaints At 7:31 AM BP 200/99, denies complaints At 8:03 AM BP 197/114, denies complaints At 10:00 AM BP 205/109. denies complaints At 10:32 AM BP 197/104 In addition, the RN documented the following: At 10:42 AM BP 221/118, denies complaints, treatment discontinued without problem At 10:45 AM post dialysis BP 230/110 There was no documentation the MD was notified of the elevated post treatment BP and no treatment for hypertension was provided. Review of the Treatment Sheet dated 9/10/21 revealed the RN documented the pre treatment BP 222/106 and at 6:24 AM at treatment start, the BP was 222/106, denies complaints. Further review of the 9/10/21 Treatment Sheet revealed the following PCT documentation: At 6:38 AM BP 222/115, denies complaints advised nurse of BP. At 7:02 AM (the next BP check), BP 214/113, denies complaints. At 7:33 AM BP 194/92, denies complaints. At 8:06 AM BP 185/99, denies complaints. There was no documentation the RN monitored the patients' the elevated BP after treatment start and addressed current BP meds compliance/refill needs per physician standing orders. Staff failed to follow physician's orders when the BP remained above 180 systolic and 110 diastolic during and post treatment. There was no documentation staff evaluated the BP med compliance or refill needs. There was no documentation staff administered Clonidine as ordered and no documentation the MD was notified for a post treatment BP 230/110. An interview was conducted with EI (Employee Identifier) # 1, Clinic Manager on 9/16/21 at 9:19 AM who confirmed staff failed to identify and treat the elevated BP per facility policy and physician orders. 3. PI # 7 was admitted to the facility 9/7/17 with diagnoses including ESRD. Review of the Treatment Sheet dated 9/4/21 revealed at 9:06 AM the PCT documented "Patient Alert; access/head covered". There was no documentation the PCT instructed PI # 7 to keep his/her head and access uncovered and 26 minutes passed until at 9:32 AM the PCT documented the access was visible. Review of the Treatment Sheet dated 9/7/21 revealed the following PCT documentation: At 9:06 AM "Patient Alert; access/head covered". At 9:33 AM "Patient Alert; access/head covered". At 10:04 AM "Patient Alert; access/head covered mask on...(treatment) Ended." There was no documentation staff were able to view the patient's head and access for a 58- minute period from 9:06 AM until 10:04 AM. Review of the Treatment Sheet dated 9/14/21 revealed the RN documented at 9:02 AM, "Patient Alert; head/access covered". There was no documentation PI # 7 was instructed to uncover his/her head and access. The documentation revealed 36 minutes passed until staff documented the access was visible at 9:38 AM. In an interview conducted on 9/16/21 at 8:59 AM, EI # 1 confirmed staff failed to ensure patient's face and accesses were visible throughout the treatment and there was no documentation patient safety education was completed. 4. PI # 3 was admitted to the facility 6/3/21 with diagnoses including ESRD. Review of the Treatment Sheet dated 9/9/21 revealed the pre treatment BP was 163/96 at 10:03 AM and treatment initiation was 10:15 AM. Further review of the 9/9/21 Treatment Sheet revealed the following

PCT documentation: At 10:33 BP 174/102 At 11:31 AM which was 57 minutes later, BP 182/103 At 12:32 PM which was 61 minutes later, BP 197/114 At 1:04 PM, BP 172/91, denies complaints At 1:42 PM BP 224/223 There was no documentation the PCT notified the RN of the elevated BP's. The PCT failed to monitor and document pulse and BP at least every 45 minutes per policy. In addition on 9/9/21 at 1:43 PM, which was greater than 3 hours into treatment with BP's greater than 180/100, the RN documented Clonidine was administered. The staff failed to follow physicians' orders for the Uncontrolled Hypertension algorithm, administer Clonidine 1 hour into the treatment for uncontrolled hypertension and determine PI # 3's current BP meds compliance and possible refill needs. Review of the Treatment Sheet dated 9/14/21 revealed the pre treatment BP was 167/98 at 10: 32 AM and treatment initiation was 11:05 AM. Further review of the 9/14/21 Treatment Sheet revealed the following PCT documentation: At 11:34 AM BP 162/102 At 12:06 PM BP 166/104 At 1:30 PM BP 159/105 At 2:05 PM BP 164/108 At 2:38 PM BP 173/106 At 3:05 PM BP 170/116 There was no documentation the PCT notified the RN of the elevated BP's during the dialysis treatment. Lastly, at 3:24 PM the RN documented BP 184/110, treatment discontinued. There was no documentation Clonidine was administered and no documentation staff evaluated/verified PI # 3's current BP med compliance and refill needs. In an interview conducted on 9/16/21 at 9:42 AM, EI # 1 confirmed staff failed to follow the patient monitoring and assessment policy and facility Uncontrolled Hypertension algorithm. 5. PI # 1 was admitted to the facility 7/24/21 with diagnoses including ESRD. Review of the Treatment Sheet dated 8/19/21 revealed the pre treatment BP was 165/98 at 10:56 AM and treatment initiation was 11:10 AM. Further review of the 8/19/21 Treatment Sheet revealed the following PCT documentation: At 11:32 AM BP 180/100, denies complaints At 12:01 PM BP 160/104, denies complaints At 1:02 PM BP 169/100, denies complaints At 1:33 PM BP 176/109, denies complaints At 2:02 PM BP 204/113 At 2:03 PM BP 185/94, denies complaints. At 2:34 PM, BP was 174/112, denies complaints At 2:35 PM, BP 159/109, denies complaints There was no documentation the PCT notified the RN of the elevated BP's. In addition, the RN documented the post treatment BP 193/105. There was no documentation Clonidine was administered and no documentation staff evaluated /verified PI # 1's current BP med compliance and refill needs. An interview was conducted on 9/16/21 at 9:02 AM with EI # 1, Clinic Manager, who confirmed staff failed to follow the patient monitoring and assessment policy and facility Uncontrolled Hypertension algorithm. 28327 6. PI # 4 was admitted to the facility on 9 /18/15 with diagnoses including ESRD. Review of the physician's orders dated 6/14 /21 revealed a target weight of 50.5 kg. Review of Treatment Sheet dated 9/1/21 revealed the post-treatment weight was 52.8 kg, which was 2.3 kg over the target weight. There was no documentation the physician was notified of the post-treatment weight. Review of the Treatment Sheet's dated 9/6/21 and 9/13/21 revealed no documentation a prime was administered prior to the start of treatment. Further review of Treatment Sheet dated 9/13/21 revealed the post-treatment weight was 52.2 kg, which was 1.9 kg over the target weight. There was no documentation the physician was notified of the post-treatment weight. An interview was conducted on 9/16/21 at 9:30 AM with EI # 1 who confirmed staff failed to notify the physician for weights over EDW and there was no documentation of a prime administered on 9/6/21 and 9 /13/21. 7. PI # 10 was admitted to the facility on 8/26/19 with diagnoses including ESRD. Review of the Orders Summary Report dated 10/30/2020 revealed, "Clonidine HCL (Hydrochloride) 0.2 mg oral during dialysis prn (as needed) - may repeat x (times) 1 hypertensive. Further review of the 9/6/21 Treatment Sheet revealed the following PCT documentation: At 1:33 PM the BP was 155/101. At 1:34 PM the BP was 155/101. At 2:03 PM the BP was 159/107. At 2:33 PM the BP was 173/101. At 2: 44 PM BP sit was 192/115 and BP stand was 172/120. At 2:45 PM the BP was 183

/113 and treatment discontinued. There was no documentation the PCT notified the RN of the elevated BP's during the dialysis treatment. There was no documentation Clonidine was administered as ordered. In an interview conducted on 9/16/21 at 9:14 AM, EI # 1 confirmed staff failed to follow the patient monitoring and assessment policy and administer Clonidine as ordered.

V0544

POC-ACHIEVE ADEQUATE CLEARANCE
CFR(s): 494.90(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of medical records, facility policies, and interviews with staff, it was determined the facility failed to ensure the staff: 1. Followed the physician order for the Blood Flow Rate (BFR) and Dialysate Flow Rate (DFR). 2. Administered mid-run and bolus Heparin as ordered. 3. Completed AMA (Against Medical Advice) forms for all dialysis treatments terminated early by the patient. This affected 8 of 10 records reviewed and did affect Patient Identifier (PI) # 2, PI # 4, PI # 6, PI # 8, PI # 10, PI # 3, PI # 7, PI # 9 and had the potential to affect all patients dialyzing at this facility. Findings include: Facility Policy: Patient Assessment and Monitoring Version: 3 Published Date: 09/29/2018 ...3. Machine Parameters and Extracorporeal Circuit 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 prescribed flow is being delivered... Facility Policy: Early Termination or Arriving Late for Treatment Published: 07/04/2012 Version: 2 The purpose...is to provide guidelines for staff when patients arrive late for their scheduled treatment time or request early termination of treatment. Background... Serious health related consequences may result from missed treatments, or terminating earlier than prescribed. Policy: Early Termination If the patient insists on terminating treatment early...not...previously approved by the patient's physician, the patient must take full responsibility for the consequences... If a patient requests to leave treatment early: ...will be referred to the supervising registered nurse (RN). The RN will evaluate the patient... discuss... reasons for requesting to terminate their treatment... If the patient's reasons... are due to complications... such as cramping, discomfort... the RN... will implement any prescribed measures to alleviate the patient's symptoms... The RN is responsible to notify the physician, and document on the AMA (Against Medical Advice) form. Requirement Documentation - AMA forms AMA forms are: Signed by the patient and witnessed by the supervising nurse... Signed with each early termination event and files in the patient's medical records. Tracked, trended and reported to the QAI (quality improvement committee monthly)... Facility Policy: Heparinization Published: 08/03/2020 Version: 4 ...The policy provides guidelines for adequate dosing and use of heparin in hemodialysis patients. ...Dose and Method of Administration The physician must order the heparin dose and method of administration... Method of Administration...Bolus at initiation and a bolus mid dialysis... Description...A bolus loading dose is administered 3-5 minutes pretreatment with a second bolus dose administered mid treatment... 1. PI # 2 was admitted to the facility 5/13/21 with diagnoses including End Stage Renal Disease (ESRD). Review of the Current Orders Report dated 8/26/21 and Hemodialysis orders dated 9/7/21 revealed a treatment time of 4 hours, BFR of 400, and DFR Autoflow 2.0, which

would be 800. Review of the Treatment Sheet dated 9/2/21 revealed the BFR was 400, and DFR was 500 from 10:59 AM to 12:30 PM. There was no documentation why the DFR was not at the ordered rate of 800. Further review of the Treatment Sheet dated 9/2/21 revealed, "hours on: 3:47 (minutes)", which was 13 minutes less treatment time than ordered. There was no documentation of an AMA as directed per the facility policy. An interview was conducted on 9/16/21 at 9:40 AM with Employee Identifier (EI) # 1, Clinic Manager, who confirmed the DFR was not run per physician orders, and early terminations were not documented per policy. 2. PI # 4 was admitted to the facility 9/18/15 with diagnoses including ESRD. Review of the Hemodialysis orders dated 6/14/21 revealed a BFR of 400, and DFR Autoflow 2.0, which would be 800. Review of the Treatment Sheet dated 9/1/21 revealed the BFR was 350, and DFR was 700 from 1:32 PM to 3:01 PM. There was no documentation why the BFR was not at the ordered rate. Review of the Treatment Sheet dated 9/3/21 revealed the BFR was 400, and DFR was 700 from 10:30 AM to 11:00 AM. There was no documentation why the DFR was not at the ordered rate of 800. Review of the Treatment Sheet dated 9/8/21 revealed the BFR was 400, and DFR was 500 from 11:39 AM to 2:31 PM, then from 2:31 PM until 3:00 the BFR was 0 and DFR was 500, then at 3:00 PM BFR was 350 and DFR was 500. There was no documentation why the BFR and DFR was not at the ordered rates. Review of the Treatment Sheet dated 9/10/21 revealed the BFR was 300, and DFR was 600 from 12:01 PM to 2:01 PM. There was no documentation why the BFR was not at the ordered rate. An interview was conducted on 9/16/21 at 9:40 AM with EI # 1 who confirmed the BFR's and DFR's were not run per physician orders. 3. PI # 6 was admitted to the facility to the facility 12/5/17 with diagnoses including ESRD. Review of the Hemodialysis orders dated 9/1/21 revealed a BFR of 350, and DFR Autoflow 2.0, which would be 700. Review of the Treatment Sheet dated 9/3/21 revealed from 6:00 AM to 7:04 AM the BFR was 350 and the DFR was 800. Then from 8:00 AM to 8:31 AM the BFR was 400 and the DFR was 800. There was no documentation why the BFR and DFR were not at the ordered rates. An interview was conducted on 9/16/21 at 9:28 AM with EI # 1 who confirmed the BFR's and DFR's were not run per physician orders. 4. PI # 8 was admitted to the facility to the facility 4/6/17 with diagnoses including ESRD. Review of the Hemodialysis orders dated 8/30/21 revealed a BFR of 350, and DFR Autoflow 2.0, which would be 700. Review of the Treatment Sheet dated 9/8/21 revealed the BFR was decreased to 0 and the DFR to 300 at 2:06 PM, then at 2:31 PM the BFR was 200 and the DFR was 400. There was no documentation why the BFR and DFR were not at the ordered rates. An interview was conducted on 9/16/21 at 9:10 AM with EI # 1 who confirmed the BFR's and DFR's were not run per physician orders. 5. PI # 10 was admitted to the facility 8/26/19 with diagnoses including ESRD. Review of the Orders Summary Report revealed orders for Heparin 2000 U (Units) IVP (Intravenous Push) mid-run every treatment dated 11/11/2020 and HD (Hemodialysis) orders dated 5/21/21, dialysis treatments 3 times a week for 4 hr 0 minutes (240-minutes). Review of the Treatment Sheet dated 9/6/21 revealed the treatment started at 10:45 AM and at 11:24 AM, staff documented the mid-run heparin was administered. This was 39 minutes into the 240-minute treatment, which is not mid-run or middle of the dialysis treatment. An interview was conducted on 9/16/21 at 9:14 AM with EI # 1 who reported the policy for mid-run Heparin was Heparin administration at the middle of the treatment, and not 39 minutes into a 240-minute treatment. EI # 1 verified the staff failed to follow the physician HD orders. 30952 6. PI # 3 was admitted to the facility 6/3/21 with diagnoses including ESRD. Review of the Current Orders Report revealed orders for Heparin 2000 Units (U) IVP (intravenous push) mid-run every treatment dated 8/12/21 and Hemodialysis (HD) orders dated 8/31/21, dialysis treatments 3 times a week for 4 hours (hr) 15 minutes (255-minutes), a BFR of 400, and DFR Autoflow 2.0, which would be 800. Review of the Treatment Sheet dated 9/4/21

revealed the treatment started at 10:34 AM and at 11:36 AM, staff documented the mid-run heparin was administered. This was 61 minutes into the 255 minute treatment, which is not mid-run or middle of the dialysis treatment. Review of the Treatment Sheet dated 9/14/21 revealed no BFR and DFR documented from 11:05 AM to 12:06 PM which was 61 minutes. There was no documentation the BFR was 400 and DFR 800 per physician orders. An interview was conducted on 9/16/21 at 9:42 AM with EI # 1 who reported the policy for mid-run Heparin was Heparin administration at the middle of the treatment, and not 61 minutes into a 255-minute treatment. Staff failed to follow the physician HD orders. 7. PI # 7 was admitted to the facility 9/7/17 with diagnoses including ESRD. Review of the Current Orders Report revealed orders for Heparin 3000 U IVP mid-run every treatment dated 6/5/21 and HD orders dated 8/31/21 for dialysis treatment for 4 hours (240 minutes) 3 times week. MR review revealed a Treatment Sheet dated 9/2/21 with documentation the treatment started at 6:32 AM and the mid-run heparin was administered at 7:12 AM, which was 40 minutes into a 240-minute treatment which was not mid-run administration. Record review revealed a Treatment Sheet dated 9/9/21 with documentation the treatment started at 6:32 AM and the mid run heparin was administered at 7:30 AM, which was 58 minutes of a 240-minute treatment which would not be mid run administration. In an interview on 9/16/21 at 8:59 AM, EI # 2, Director of Operations reported mid run of a 4- hour treatment would be 2 hours (120 minutes) and Heparin was not administered according to physician orders. 8. PI # 9 was admitted to the facility 4/16/2020 with diagnoses including ESRD. Review of the Rounding Report revealed physician orders dated 4/17/21 for Heparin, 2000 U bolus every treatment, and orders dated 4/20/21 for Heparin catheter lock arterial and venous port 1000 U/ml (milliliter) 1.8 post dialysis every treatment. Review of the Treatment Sheet dated 8/25/21 revealed an Ultrafiltration treatment was performed via a central venous catheter. There was no documentation staff administered the Heparin bolus and the catheter arterial/venous lock per physician orders. In an interview on 9/16/21 at 8:54 AM, EI # 1 confirmed there was no documentation Heparin was administered as ordered.

V0545

POC-EFFECTIVE NUTRITIONAL STATUS

CFR(s): 494.90(a)(2)

The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.

This STANDARD is not met as evidenced by:

Based on medical record (MR) review and interview with the staff, it was determined the facility failed to ensure: 1. The IDT (interdisciplinary team) followed the patient Plan of Care (POC) for albumin management, monitored monthly nutrition labs and addressed the nutrition needs with a rapid decline in the albumin level. 2. The staff administered nutritional supplementation as ordered. This affected PI (Patient Identifier) # 5 and PI # 1 in 2 of 10 records reviewed and had the potential to negatively affect all patients who dialyzed at the facility. Findings include: 1. PI # 5 was admitted to the facility on 7/3/19 with diagnoses including Diabetes Mellitus with Diabetic Nephropathy and ESRD (End Stage Renal Disease). Review of the Patient POC dated 4/29/21 included the following nutritional goals, Albumin \geq (greater than equal to) 4.0 g/dL (gram/deciliter); Goal Due: 09/30/21. Open 03/22/21-Albumin 3.9-intervention monitor albumin and other nutrition related labs monthly. Review of the

Rounding Report printed on 7/12/21 revealed the following Albumin laboratory results: 7/07/21- 3.8 g/dL 8/04/21 4.0 g/dL 9/01/21 - 3.1 g/dL Review of the Treatment Sheets dated 9/6/21, 9/8/21, 9/10/21, and 9/13/21 revealed no documentation nutritional supplementation was provided for the declining albumin level. There was no physician's order for nutritional supplementation to address the 9/1/21 3.1 albumin level. An interview was conducted with EI (Employee Identifier) # 2, Director of Operations on 9/16/21 at 9:19 AM who confirmed the IDT failed to follow the 4/29/21 POC, monitor the monthly labs and provide nutritional supplementation to address the albumin level less than 4.0. g/DL. 2. PI # 1 was admitted to the facility 7/24/21 with diagnoses including ESRD. Review of the Orders Summary Report revealed physician orders dated 8/10/21 for the nutritional supplement, Liquacel -1 ounce by mouth every dialysis treatment. Review of the 8/28/21 Treatment Sheet revealed the Albumin laboratory result was 2.8 g/dL on 8/5/21. There was no documentation Liquacel was provided and no documentation the patient refused Liquacel on 8/28/21. An interview was conducted on 9/16/21 at 9:02 AM with EI # 1, Clinic Manager who confirmed there was no documentation of the Liquacel was administered as ordered.

V0550

POC-VASCULAR ACCESS-MONITOR/REFERRALS
CFR(s): 494.90(a)(5)

The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.

This STANDARD is not met as evidenced by:

Based on observations, review of medical record (MR), policy and procedure, and staff interviews, it was determined the facility failed to ensure the staff followed their own policy and procedure for care of an AVF/AVG (Arteriovenous Fistula/Graft). This affected PI's (Patient Identifier) # 7, PI # 8, PI # 10, in 3 of 6 records reviewed for patients with an AVF/AVG (arteriovenous fistula/graft and this had the potential to affect all patients with an AVF/AVG. Findings Include: Facility Policy: Access Assessment and Cannulation Published: 08/22/2018 Version: 1 Purpose...of this procedure...provide guidance for placements of needles in an AV Fistula or AV Graft...for hemodialysis. ...Skin Disinfection Step 1. Disinfect cannulation site as follows using any of the disinfectants below: 70 % isopropyl alcohol pad... Povidone Iodine pad... 2% Chlorhexadine and 70% alcohol... 1. PI # 7 was admitted to the facility 9/7/17 with diagnoses including End Stage Renal Disease(ESRD). Review of the Treatment Sheets dated 9/2/21, 9/9/21, 9/11/21, and 9/14/21 revealed staff documented the AVF was "Cleaned with chlorhexidine." MR review revealed no physician's order for chlorhexadine. There was no reason documented why 70 % isopropyl alcohol, Povidone Iodine, or 2% Chlorhexadine and 70% alcohol was not used in 4 of 6 treatment sheets reviewed. In an interview on 9/16/21 at 8:59 AM, EI (Employee Identifier) # 2, Director of Operations reported chlorhexadine was not an accepted AVF site skin disinfectant. Staff failed to follow the facility procedure for AVF skin disinfection. 28327 2. PI # 8 was admitted to the facility 4/6/17 with diagnoses including ESRD. Review of the Treatment Sheets dated 9/10/21 and 9/13/21 revealed staff documented the AVF was "Cleaned with chlorhexidine." MR review revealed no physician's order for chlorhexadine. There was no reason documented why 70 % isopropyl alcohol, Povidone Iodine, or 2% Chlorhexadine and

70% alcohol was not used in 2 of 6 treatment sheets reviewed. In an interview on 9/16/21 at 9:10 AM, EI # 1, Clinic Manager, reported chlorhexadine was not an accepted AVF site skin disinfectant. Staff failed to follow the facility procedure for AVF skin disinfection. 3. PI # 10 was admitted to the facility 8/26/19 with diagnoses including ESRD. Review of the Treatment Sheets dated 9/1/21, 9/3/21, 9/6/21, 9/8/21, 9/10/21 and 9/13/21 revealed staff documented the AVF was "Cleaned with chlorhexidine." MR review revealed no physician's order for chlorhexadine. There was no reason documented why 70 % isopropyl alcohol, Povidone Iodine, or 2% Chlorhexadine and 70% alcohol was not used in 6 of 6 treatment sheets reviewed. In an interview on 9/16/21 at 9:14 AM, EI # 1 reported chlorhexadine was not an accepted AVF site skin disinfectant. Staff failed to follow the facility procedure for AVF skin disinfection.

V0551

POC-VA MONITOR/PREVENT FAILURE/STENOSIS
CFR(s): 494.90(a)(5)

The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.

This STANDARD is not met as evidenced by:

Based on review of facility policy, medical records (MR) and staff interviews, it was determined the facility failed to ensure staff documented the presence/absence of a bruit and thrill (B/T) in 4 of 10 records reviewed with an AVF/AVG (arteriovenous fistula/graft). This affected PI (Patient Identifier) # 2, PI # 8, PI # 10, PI # 7, and had the potential to negatively affect all patients who dialyzed at the facility. Findings include: Facility Procedure: Access Assessment and Cannulation Published: 08/22/2018 Version: 1 Purpose ...of this procedure is to provide guidance for placement of needles in an AV (arteriovenous) Fistula or AV Graft... Policy New Access Care and Cannulation Evaluation and preparation of the access will be performed routinely prior to cannulation at each dialysis session. ...assign clinical staff for the initial cannulations based on experience and expertise. Check fistula for adequate bruit and thrill to confirm patency. Check for signs of infection. ...Perform skin disinfection as outlined in policy... Assessment of Vascular Access Follow the steps below to access the vascular access: 5. LOOK: Skin Discoloration/Redness/Bruising/lesion Hematomas Extremity or Other Swelling ...Greater than expected redness...Swelling 6...LISTEN: Bruit high pitch/whistle Bruit not present throughout access ...Document in eCC ("e-cube"-the facility electronic medical record documentation software) 7. FEEL: Pulse not soft/not easily compressible Thrill not strong at anastomosis Thrill not present throughout access Document in eCC. 1. PI # 2 was admitted to the facility 5/13/21 with diagnoses including End Stage Renal Disease (ESRD). MR review revealed Current Orders Report dated 8/26/21 Hemodialysis orders dated 9/7/21 for dialysis 3 times a week via an AVF. Review of the Treatment Sheets dated 9/2/21, 9/4/21, 9/7/21, and 9/14/21, 4 of 6 treatments reviewed, revealed no documentation staff assessed the condition of the AVF for the presence of a B/T or abnormal findings. An interview was conducted on 9/16/21 at 9:40 AM with Employee Identifier (EI) # 1, Clinic Manager, who confirmed the staff failed to follow the facility procedure for access site assessment. 2. PI # 8 was admitted to the facility 4/6/17 with diagnoses including ESRD. MR review revealed Hemodialysis orders dated 8/30/21 for dialysis 3 times a week via an AVF. Review of the Treatment Sheets dated 9/1/21, 9/3/21, 9/6/21, 9/8/21, 9/10/21, and 9/13/21, 6 of 6 treatments reviewed, revealed no documentation staff assessed the condition of the AVF for the presence of a B/T or abnormal findings. An interview was conducted on 9/16/21 at 9:10 AM with EI # 1 who confirmed the staff failed to follow the facility procedure for access site

assessment. 3. PI # 10 was admitted to the facility 8/26/19 with diagnoses including ESRD. MR review revealed Hemodialysis orders dated 5/21/21 for dialysis 3 times a week via an AVF. Review of the Treatment Sheets dated 9/1/21, 9/3/21, 9/6/21, 9/8/21, 9/10/21, and 9/13/21, 6 of 6 treatments reviewed, revealed no documentation staff assessed the condition of the AVF for the presence of a B/T or abnormal findings. An interview was conducted on 9/16/21 at 9:14 AM with EI # 1 who confirmed the staff failed to follow the facility procedure for access site assessment. 30952 4. PI # 7 was admitted to the facility 9/7/17 with diagnoses including ESRD. Review of the Current Orders Report revealed Hemodialysis orders dated 8/5/21 for 3 x (times) a week dialysis treatments via an AVF. Review of the Treatment Sheets dated 9/4/21, 9/7/21, and 9/11/21, which was 3 of 6 treatments reviewed revealed no documentation of an AVF assessment which included the presence/absence of a B/T. During an interview conducted on 9/16/21 a 8:59 AM, EI # 1 confirmed staff failed to follow facility policy and perform and document AVF assessment findings.

V0634

QAPI-INDICATOR-MEDICAL INJURIES/ERRORS
CFR(s): 494.110(a)(2)(vi)

The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification.

This STANDARD is not met as evidenced by:
Based on observation, facility policy and staff interviews, it was determined the facility failed to ensure staff reported, and documented an adverse event per facility policy. This affected Patient Identifier (PI) # 18, in 1 of 2 patient care observations conducted for AVF/AVG (arteriovenous fistula/graft) treatment initiation and had the potential to negatively affect all patients who dialyzed at the facility. Findings include: Facility Policy: Patient Adverse Event Reporting and Documentation Published: 01/02/2019 Version: 3 Purpose: The purpose of this policy is to provide guidelines for all clinical staff on reporting and documentation of patient related adverse events, serious adverse events, near misses and unsafe conditions to: - Promote a culture of safety. - Provide a standardized process for the identification and management of all patient related safety events ... Policy: Any time an adverse event (AE) or serious adverse event (SAE) occurs, staff are required to report, document, and review the event as indicated within this policy. All staff are responsible for timely completion of the policy requirements. Reporting: All employees are required to immediately report both AEs and SAEs to their supervising manager... Documentation: All adverse or SAEs shall be documented in the following: - Patient medical record - Adverse Event Data Entry Site ... Documentation of patient safety events: - Shall be factual, complete and concise. - Shall include patient assessment and represent an accurate recording of the events, times, interventions and result of interventions. 1. On 9/14/21 at 10:00 AM at station 17, EI (Employee Identifier) # 5, Patient Care Technician, initiated dialysis treatment for a 2 K (Potassium) 2.5 Ca (calcium) dialysis bath. At 10:37 AM EI # 5 placed a jug bath labeled 3 K 2.5 Ca at the base of the dialysis machine at station 19 for PI # 18. The surveyor asked EI # 5 why the dialysis bath was changed? EI #5 stated, "I just looked at the orders and this is the bath ordered". EI # 5 failed to test the dialysate pH when the bath acid concentrate was changed from 2 K to 3 K. In an interview on 9/16/21 at 8:25 AM with EI # 1, Clinic Manager, the surveyor requested documentation for AEs/near misses reported for 9/14/21. EI # 1 reported no AEs/near miss documentation was completed on 9/14/21. The surveyor reported the 9/14/21 10:00 AM observation at station 17 and the interview with EI # 5. EI # 1 confirmed EI # 5 failed to follow facility policy and

test the dialysate pH when the bath acid concentration was changed and failed to complete AE event documentation for treatment initiation with an incorrect dialysis bath.