

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  012515	<b>(X3) Date Survey Completed</b>  04/20/2023
<b>Name of Provider or Supplier</b>  Fresenius Medical Care Opelika	<b>Street Address, City, State</b>  2609 Village Professional Drive, Suite 2, Opelika, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>  (Each deficiency should be preceded by full regulatory or LSC identifying information)
<b>E0000</b>	A recertification survey was conducted on 4/18/23 to 4/20/23 at Fresenius Medical Care Opelika. Standard level deficiencies were cited for Emergency Preparedness which require an acceptable plan of correction.
<b>E0038</b>	ESRD EP Training Program  494.62(d)(1): Condition for Coverage: (d)(1) Training program. The dialysis facility must do all of the following: (i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles. (ii) Provide emergency preparedness training at least every 2 years. Staff training must: (iii) Demonstrate staff knowledge of emergency procedures, including informing patients of- (A) What to do; (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and (D) How to disconnect themselves from the dialysis machine if an emergency occurs. (iv) Demonstrate that, at a minimum, its patient care staff maintains current CPR certification; and (v) Properly train its nursing staff in the use of emergency equipment and emergency drugs. (vi) Maintain documentation of the training. (vii) If the emergency preparedness policies and procedures are significantly updated, the dialysis facility must conduct training on the updated policies and procedures.  This STANDARD is not met as evidenced by: Based on a review of the End Stage Renal Disease Core Survey Facility Worksheet:

Personnel File, facility personnel file, and interview, it was determined the facility failed to ensure EI (Employee Identifier) # 3, RN (Registered Nurse), in one of three RN files reviewed, completed training for the facility emergency preparedness policies and procedures and demonstrated knowledge of facility emergency procedures. This had the potential to negatively affect all patients who dialyze at the facility. Findings Include: Review of the Core Survey Facility Worksheet: Personnel File documentation dated 4/19/23 revealed EI # 3's date of hire was 5/1/22. There was no documentation EI # 3 completed initial emergency preparedness training. Review of EI # 3's Education Transcript dated 4/18/2020 to 4/18/23 revealed no documentation that initial/annual training on the facility emergency preparedness policies and no documentation emergency procedures were demonstrated. In an interview on 4/20/23 at 10:50 AM, EI # 1, Director of Operations confirmed there was no emergency preparedness training documentation for EI # 3.

**V0000**

'CORE' Based on the recertification survey conducted 4/18/23 to 4/20/23, Fresenius Medical Care Opelika was not in compliance with the Conditions for Coverage (Cfc) at 494.30- Infection Control and Cfc at 494.90-Patient Plan of Care and related standards.

**V0101**

**COMPLIANCE WITH FED/STATE/LOCAL LAWS**  
CFR(s): 494.20

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.

This STANDARD is not met as evidenced by:  
Based on review of the Alabama Department of Public Health for Rules for End Stage Renal Disease Treatment and Transplant Centers Chapter 420-5-5, the facility Absence and Hospitalization, Discharged to the Hospital Report documentation, and staff interview, it was determined the facility failed to follow State Licensure Rules for End Stage Renal Disease for reporting all unusual occurrences to the State Survey Agency (SSA) for unscheduled transports to a hospital. This did affect eight of ten unscheduled transfers and had the potential to affect all patients served by the facility. Findings include: Rules of Alabama State Board of Health Alabama Department of Public Health Chapter 420-5-5 End Stage Renal Disease Treatment and Transplant Centers 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 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). Review of the facility Absence and Hospitalization, Discharged

to the Hospital Report dated 4/18/22 to 4/18/23, revealed a total of twelve patients were discharged to the hospital. The SSA was notified of only two of the twelve transferred/discharged from the facility by emergency transport to the hospital. An interview was conducted on 4/20/23 at 11:50 AM with EI (Employee Identifier) # 12, Interim Clinical Manager, who verified eight patients documented on the Absence and Hospitalization, Discharged to the Hospital Report were transferred from the facility to the hospital per emergency/ambulance service. EI # 12 confirmed the eight transfers were not reported as unusual occurrences to the SSA over the past 12 months.

**V0110**

**CFC-INFECTION CONTROL**  
CFR(s): 494.30

This CONDITION is not met as evidenced by:  
Based on observations, facility policies and procedures, the End Stage Renal Disease Core Survey Facility Worksheet: Personnel File, personnel file, 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: V 111, V 113, V 117, V 122, V 126, V 130, V 132, V 143, and V 147.

**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 observations, facility policies and procedure, and interviews, it was determined the facility failed to ensure: 1. Staff followed the facility procedure for bleach preparation to prevent transmission of bloodborne pathogens. 2. Staff followed facility policy for antisepsis prior to cannulation of the dialysis access site in one of two observations for Access of AV (arteriovenous) Fistula or Graft for Initiation of Dialysis which included PI (Patient Identifier) # 13. This had the potential to negatively affect all patients who dialyze at this facility. Findings include: Facility Procedure: Mixing Bleach Published: 08/25/2020 Version: 4 Procedure ...2...measure amount of water into labeled opaque container...ensure proper concentration: 1:100 = 1- part bleach plus 99 parts water 1:10 =1- part bleach plus 9 parts water ...4. Label opaque container with "Bleach Solution", strength of solution, date and time prepared and your initials. 5. Cover opaque container with lid. 6. Discard solution daily at end of treatment... Facility Policy: Access Assessment and Cannulation Policy Number: 45178 Version 3 Published 7/5/22 Purpose: The purpose of this procedure is to provide guidance for ...placement of needles in an AV Fistula or AV Graft... Background: Before each treatment...The access must be prepared properly for needle placement to prevent bacteria from entering the bloodstream through the skin... Skin Disinfection: 1. Disinfect cannulation sites as follows using any of the disinfectants below: 70% (percent) alcohol pad: Using gentle friction, clean the access site ...for 30 seconds and allow to dry before cannulating. 1. During observations of care on the in-center treatment room on 4/18/23, the surveyor observed the following: At 9:15 AM, the 1:100 bleach containers located across from station 12 and station 13 with solution

present was uncovered and no date prepared was documented on the container. An interview was conducted on 4/18/23 at 9:15 AM during the observation with EI (Employee Identifier) # 14, CCHT (Certified Clinical Hemodialysis Technician) who confirmed the bleach was uncovered and no preparation date was documented on the bleach container. At 10:10 AM, the 1:100 bleach container located across from station 23 did not have the preparation date documented on the bleach container. At 10:40 AM, 11:00 AM, and 11:50 AM, the 1:100 bleach container located across from station's 12/13 remained uncovered. On 4/19/23 at 9:00 AM, the surveyor observed the 1:100 bleach container across from station's 18 and 13 were not covered. EI # 15, CCHT, present during the observation, reported there was no lid for the bleach container and confirmed the bleach container was not covered. On 4/19/23 at 9:03 AM, the bleach container located next to the TriStation was uncovered. An interview was conducted on 4/19/23 at 9:03 AM with EI # 15, CCHT, who was present at the TriStation during the observation confirmed the bleach container was uncovered. An interview was conducted on 4/20/23 at 10:50 AM with EI # 1, Director of Operations who confirmed staff failed to follow the facility bleach preparation procedure. 41624 2. During an observation of care on 4/18/23 at 10:17 AM at station 10, the surveyor observed EI # 16, CCHT, perform access site antisepsis to PI (Patient Identifier) # 13's AV Fistula or Graft site. EI # 16 utilized an alcohol prep pad to cleanse access site number one in a circular motion for five seconds, then immediately accessed the site with the needle. EI # 16 then utilized a second alcohol prep pad, cleansed access site number two in a circular motion for five seconds, then immediately accessed the site with a needle. EI # 16 failed to cleanse the access sites for 30 seconds and wait for the alcohol to dry per policy before accessing the sites with a needle. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1 who confirmed EI # 16 did not perform antisepsis and cannulate the access sites per policy.

**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 the facility policies, and staff interviews, it was determined the facility failed to ensure : 1. Patients performed hand hygiene after holding exit sites prior to exiting the clinic. This included two of three observations for discontinuation of dialysis and post dialysis access care for AV (arteriovenous) fistula or graft which included Patient Identifier (PI) # 16, and PI # 17. 2. Staff performed hand hygiene before administering IV (intravenous) medication, in one of four observations for medication preparation and administration which included PI # 13. This had the potential to negatively affect all patients who dialyze at the facility, staff, and visitors. 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... Hand Hygiene: Patients Patients should perform hand hygiene if able, prior to and after each dialysis treatment. ...Gloves must be provided to patients when performing procedures which risk exposure to blood or body fluids, such as...holding access sites

post treatment to achieve hemostasis. To help ensure the prevention of cross contamination to their family members or other patients, hand hygiene must be performed. Facility Policy: Medication Preparation and Administration Published: 4/5/21 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 or administering medications Aseptic technique will be used to prepare and administer IV medications. 1. During observations of care on the treatment floor on 4/18/23 from 9:20 AM to 10:27 AM for discontinuation of dialysis and post dialysis access care for AV Fistula or Graft the following were observed: a. PI # 16 held pressure over his/her access site with a gloved hand. Once hemostasis was achieved, PI # 16 removed his/her glove and exited the treatment area at 9:35 AM without performing hand hygiene. b. PI # 17 held pressure over his/her access site with a gloved hand. Once hemostasis was achieved, PI # 17 removed his/her glove and exited the treatment area at 10:27 AM without performing hand hygiene. The facility staff failed to have PI # 16 and PI # 17 perform hand hygiene per policy. In an interview conducted on 4/20/23 at 10:40 AM, Employee Identifier (EI) # 1, Director of Operations (DO), confirmed the dialysis patients should have performed hand hygiene before exiting the facility per policy. 2. During an observation of medication preparation and administration on 4/18/23 at 11:12 AM, EI # 3, Registered Nurse, prepared IV medication for PI # 13. EI # 3 sanitized his/her hands, donned gloves, and prepared IV Venofer 50 mg (milligram), exited the medication preparation area and entered station 10. EI # 3 administered the IV Venofer wearing the same gloves as used during medication preparation. EI # 3 failed to remove his/her gloves, perform hand hygiene before IV Venofer administration. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1, who confirmed staff must perform hand hygiene prior to administering IV medication. 30952

**V0117**

**IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS**  
CFR(s): 494.30(a)(1)(i)

Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.

This STANDARD is not met as evidenced by:

Based on observation, facility policy, and interview, it was determined the staff failed to ensure only individual patient's medications were taken to their dialysis station. This did affect one of one random observation on the treatment floor and had the potential to negatively affect all patients who dialyze at the facility. Findings include: Facility Policy: Medication Preparation and Administration Published: 4/5/21 Version: 6 Purpose: To administer medications with the goals of staff and patient safety, optimal therapeutic response, and infection control. ...Infection Control Medications shall be prepared...away from dialysis patient stations and delivered

separately to each patient. 1. During an observation on the treatment floor on 4/18/23 at 10:29 AM, Employee Identifier (EI) # 4, Registered Nurse (RN) entered the patient treatment floor around the area of stations 5 and 10 with two prefilled/prepared IV (Intravenous) medications in hand. EI # 4 placed one of the IV prefilled/prepared syringes on the chairside table of station 10, then exited the station. EI # 4 then proceeded to station 5 and placed the remaining IV prefilled/prepared syringe on the chairside table of station 5. EI # 4 failed to ensure only individual patient's medications were taken to their dialysis station. An interview was conducted on 4/20/23 at 10:50 AM with EI # 1, Director of Operations, who confirmed staff failed to follow the facility policy and deliver medications separately to each patient.

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 procedure, and interview, it was determined the facility failed to ensure: 1. Staff cleaned and disinfected the dialysis station after patient treatments. This affected two of two observations of the cleaning and disinfection of dialysis station. 2. Staff cleaned one of one blood spots at a dialysis station in the isolation unit. This affected Patient Identifier (PI) # 20, one of one patients dialyzing in the isolation unit, and had the potential to negatively affect all patients susceptible to hepatitis B virus, visitors and staff. Findings include: Facility Policy: Cleaning and Disinfection of the Dialysis Station Reference Number: 47806 Published: 11/07/2022 Version: 13 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 Background The Centers for Medicare and Medicaid Services (CMS) has regulations that in order to prevent contamination, a dialysis station must be cleaned and disinfected between dialysis patients... Definition Dialysis Station: Area including the dialysis machine, chair/bed and other reusable equipment or supplies utilized during dialysis treatment... Equipment in the dialysis station may include... the following: Dialysis machine /cycler and attachments such as IV (Intravenous) pole, B/P (Blood Pressure) cuff... Chair/bed... Individual television and remote, dialysis wall box. General Cleaning The dialysis station could become contaminated with blood and other body fluids during treatment. 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. Procedure Follow the steps below to disinfect the dialysis station after each dialysis treatment: Step: ...3. Use a cloth wetted with 1:100 bleach solution... to clean and disinfect the dialysis station (chair/bed, tables, machine, television, IV pole, B/P cuff... wall behind chair... 4. Clean all surfaces. Make the surfaces glisteningly wet and allow to air dry... 5. ... While wiping, remember to wipe all surfaces of the machine including the air detector chamber, blood pump casing... and wherever the extracorporeal circuit was in contact with the machine. Work Surface Cleaning and Disinfection with Visible Blood less than ten milliliters and Other Potentially Infectious Material using Bleach solutions:

Use 1:100 bleach solution to clean surfaces with visible blood. After cleaning up all visible blood, use a new cloth with 1:100 bleach solution for a second cleaning of the surface.... Clean and disinfect any surfaces contaminated with blood or other potentially infectious material immediately or as soon as feasible. 1. An observation was conducted on 4/18/23 at 9:40 AM to observe Employee Identifier (EI) # 16, Certified Clinical Hemodialysis Technician (CCHT) perform cleaning and disinfection of station 7. EI # 16 failed to clean and disinfect the hanson connectors, the blood pump casing, and the undersides of both patient treatment chair trays. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1, Director of Operations (DO), who confirmed staff failed to follow the facility policy and procedure for dialysis station cleaning/disinfection. 2. An observation was conducted on 4/18/23 at 9:55 AM to observe EI # 14, CCHT perform cleaning and disinfection of station 18. EI # 14 failed to clean and disinfect the television, television arm, and the counter behind the station. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1 who confirmed staff failed to follow the facility policy and procedure for dialysis station cleaning/disinfection. 3. During observation of the isolation room on Tuesday, 4/18/23 at 12:25 PM, a large (slightly larger than size of quarter) spot of blood was observed on the floor underneath the treatment chair. Review of the facility daily patient schedule revealed the isolation room was utilized on Monday, Wednesday and Friday's for isolation patient PI # 20. The facility staff failed to immediately clean the blood spill and disinfect the isolation station per policy. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1, who confirmed staff failed to follow the facility policy and procedure to immediately clean the blood spill and disinfect the isolation station. 30952

**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, and interview, it was determined the facility failed to ensure all susceptible patients were vaccinated or a declination form was obtained per policy. This affected one of one new patient, including Patient Identifier (PI) # 1, and had the potential to negatively affect all patients served by the facility. Findings include: Facility Policy: Patient Guidance for Hepatitis B Vaccination Policy Number: 47676 Published 2/7/22 Version 5 Purpose: Provide guidance for hepatitis B vaccination Hepatitis B Vaccine Guidelines: The Hepatitis B vaccine (HBV) shall be offered to all susceptible patients... ..Patients shall sign a vaccination consent/declination form. ...A protective antibody response is 10 or more multigenerational units per milliliter... Declination: ...Each offering of the vaccine should be documented in the patient's medical record. 1. PI # 1 was admitted to the facility on 3/4/23 with a diagnosis of End Stage Renal Disease. Review of the laboratory (lab) results collected 3/7/23 revealed documentation of an Anti-HBs of below 10 (not immune-susceptible to hepatitis b virus). Review of the MR printed on 4/19/23 revealed no documentation PI # 1 was offered the HBV vaccination per the facility policy. An interview was conducted on 4/20/23 at 9:40 AM with Employee Identifier # 1, Director of Operations, who confirmed there was no documentation PI # 1 was offered the HBV 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 observation, review of facility policy, and interview, it was determined the facility failed to ensure all equipment used in the isolation room was designated and labeled for "isolation" only. This had the potential to affect all Hepatitis B susceptible patients and staff at the facility. Findings include: Facility Policy: Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+) Published 3/20/13 Policy Number: None Version: Seven Purpose: To prevent transmission of Hepatitis B 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., should be labeled "isolation" and not routinely removed. 1. On 4/18/23 at 12:25 PM an observation of the facility isolation room was conducted which included inspection of the equipment/supplies housed in the isolation unit. There was no isolation label on the following equipment /supplies: Patient treatment chair One hemodialysis machine # (number) 4 Two containers for 1 to 100 bleach concentration One gallon size container of Pure Bright ultra bleach One Rolling Sharps container One Rolling Bio-hazard can Two Treatment stools One Spectra Last centrifuge One small refrigerator One 60 milliliter (ml) bottle of Myron L pH-ORP (potential hydrogen-oxidation reduction potential) sensor storage solution One 60 ml bottle of Mesa Labs 10.0 pH standard buffer solution One 60 ml bottle of Mesa Labs 14.0 mS/Cm (milli Siemens per centimeter) conductivity solution One 32 ounce bottle of Myron L 442-300 TDS (total dissolved solids)/Conductivity standard solution One two shelf stainless steel cart storing various supplies, including dialyzers, fistula needles, barriers, tape, needles, gloves, syringes, and tubing. An interview was conducted on 4/20/23 at 10:40 AM with Employee Identifier # 1, Director of Operations who confirmed all equipment and supplies in the isolation room were not labeled and designated for isolation only use.

V0132

IC-TRAINING & EDUCATION

CFR(s): 494.30(a)(1)(i)

Infection Control Training and Education Infection control practices for hemodialysis units: intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices.

This STANDARD is not met as evidenced by:

Based on personnel file review, ESRD (End Stage Renal Disease) Core Survey Facility Worksheet: Personnel File, facility policy, and interview, it was determined the facility failed to ensure staff completed annual infection control training for one of three CCHT (Certified Clinical Hemodialysis Technician) files reviewed, including EI (Employee Identifier) # 7, CCHT. This had the potential to affect all patients served by the facility. Findings include: Facility Policy: Knowledge, Skills and Competency for Clinical Staff Published: 10/12/2021 Version: 3 Purpose ...FKC (Fresenius Kidney Care) provides all clinical field employees with initial and ongoing development and evaluation of the knowledge and skills essential for a highly functional and well-trained workforce. Background The following are...required clinical topics covered

during training... -Initial, Annual, and One-time Role Specific Training -Initial, Annual, and One-time Role Specific Knowledge Evaluation -Initial, Annual, and One-time Role Specific Skills Evaluation ...Policy Employees are required to pass all exams, including an initial and annual exam. Employees are required to successfully complete all skills requirements, including an initial and annual skills validation, within the given timeframe. Employees without current documented competency within the past 365 days may be removed from performing independent direct patient care (DPC) until competency is demonstrated and documented. ...Documentation Completion dates are entered...for ... annual exam and skills validation...Annual Skills Validation.... 1. During observations of care on 4/19/23 from 8:25 AM until 9:10 AM, the surveyor observed EI # 7, CCHT providing care for in-center patients including care of the hepatitis B positive patient dialyzing in the isolation room. A review of the 'ESRD Core Survey Facility Worksheet: Personnel File' dated 4/19/23 revealed EI # 7's, date of hire was 2/26/01 and the Infection Control Training date was 11/17/2020. On 4/20/23 at 8:50 AM after additional training documentation was provided by EI # 13, Administrative Assistant, a review of EI # 7's Education Transcript dated 4/18 /2020-4/18/23 revealed the Infection Control Fundamentals Training completion date was 11/17/2020. Further review of training documentation revealed EI # 7's Direct Patient Care-Annual Skills Validation Checklist was last completed 6/30/21 and included direct observation of seven infection control skill components including hepatitis B precautions and isolation techniques. EI # 7's Infection Control training and Infection Control Skills Validation was not completed annually per facility policy. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1, Director of Operations who confirmed there was no documentation EI #7 completed annual Infection Control training and annual skills validation for infection control were demonstrated.

**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 facility policy, and interviews, it was determined the facility staff failed to ensure: 1. All intravenous (IV) medications were secured and stored according to facility policy. 2. A new needle and syringe was used during entry into a multi-dose vial (MDV). This affected one of four observations for IV medication preparation and administration and included PI # 19, and two random observations of unsampled patients and had the potential to negatively affect all patients served by this facility. Findings include: Facility Policy: Medication Preparation and Administration Published: 4/5/21 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 or administering medications Aseptic technique will be used to prepare and administer IV medications. ...Always use a sterile syringe and needle when entering a vial...If...vial is multi-use, a different syringe must be used for entry... Securement The following steps must be taken for the securement: All medications will be kept in a locked cabinet except when in use. 1. During a tour of the treatment floor on 4/18/23 at 8:30 AM, the surveyor observed seven unopened IV medication vials, one open bottle of Heparin and three oral

medication bottles sitting on the counter in the medication preparation (prep) area. There was no Registered Nurse (RN) at the medication counter. In an interview conducted on 4/18/23 at 11:50 AM, the Employee Identifier (EI) # 4, RN was present at the medication prep counter and the surveyor asked EI # 4 if the IV medications were allowed to be left on the counter, not in the medication cabinet? EI # 4 responded he/she did not know the answer. 2. During observations on the treatment floor on 4/18/23 at 10:29 AM, EI # 4, RN entered the patient treatment floor around the area of stations 5 and 10 with prefilled/prepared IV medications in hand. EI # 4 placed an IV syringe on the chairside table of station 10, then exited the station leaving the IV medication unattended. EI # 4 entered station 5 and placed an IV syringe on the chairside table of station 5, exited the station, leaving the IV medication unattended. EI # 4 returned to station 10 at 10:30 AM and administered the IV medication to an unsampled patient. EI # 4 returned to station 5 at 10:35 AM and administered the IV medication to an unsampled patient. EI # 4 failed to ensure IV medications were stored and secured per policy, leaving the IV medication at station 10 unattended for six minutes, and leaving the IV medication at station 5 unattended for approximately ten minutes. An interview was conducted on 4/20/23 at 10:50 AM with EI # 1, Director of Operations who confirmed the IV medications were not secured per policy. 3. An observation was conducted on 4/18/23 at 1:05 PM of parenteral (medications given by injection or infusion) medication preparation and administration by EI # 3, RN, for PI # 19. EI # 3 was observed entering a MDV of Hectoral with a syringe and needle, withdrawing approximately one milliliter (ml) of the medication, then re-entering the MDV with the same needle and syringe to withdraw an additional 0.5 ml. EI # 3 failed to follow facility policy and utilize a different syringe for each entry into the MDV. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1 who confirmed per facility policy the RN should have utilized a different syringe before entering the MDV a second time. 41624

**V0147**

**IC-STAFF EDUCATION-CATHETERS/CATHETER CARE**  
CFR(s): 494.30(a)(2)

Recommendations for Placement of Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters. II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients. VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].

This STANDARD is not met as evidenced by:

Based on observations, review of the facility procedure, and staff interviews, it was determined the facility failed to ensure staff performed Central Venous Catheter (CVC) exit site care according to facility procedure in two of two CVC observations. This affected Patient Identifier (PI) # 4, and PI # 11 and had the potential to negatively affect all patients with CVC's who dialyze at this facility. Findings include: Facility Procedure: Changing the Catheter Dressing Published: 05/02/2022 Reference Number: 45664 Version: 7 Purpose: The purpose of this policy is to provide

instruction for cleaning the hemodialysis catheter exit site... Supplies ...1 package-2% chlorhexidine (CHG) 70% isopropyl alcohol swabs stick... Cleaning the Site: Follow the steps below to clean the catheter exit site: ...2. Remove swab stick from package... 2% CHG and 70% alcohol (Chloraprep): Using gentle back and forth friction, clean the exit site beginning in the center...and continuing outward...for 30 (thirty) seconds and allow to dry a minimum of 30 seconds... 1. During an observation of CVC exit site care conducted at station 4 on 4/18/23 at 12:10 PM, Employee Identifier (EI) # 4, Registered Nurse (RN) cleaned PI # 4's CVC exit site with one Chloraprep swab stick for five seconds, utilized a second Chloraprep swab stick and cleaned the exit site again for an additional eight seconds, cleaning the exit site for a total of 13 seconds. EI # 7 failed to clean the exit site with Chloraprep for 30 seconds. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1, Director of Operations (DO), who confirmed staff failed to follow the CVC exit care procedure. 30952 2. During an observation of care on 4/18/23 at 12:12 PM, the surveyor observed EI # 3, RN, perform CVC exit site care and initiation of dialysis on PI # 11. During exit site care, EI # 3 cleansed the CVC exit site with Chloraprep antiseptic swab stick for 20 seconds. EI # 3 failed to clean the CVC exit site with Chloraprep for 30 seconds per facility procedure. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1, who confirmed staff failed to follow the CVC exit site care procedure.

**V0196**

**CARBON ADSORP-MONITOR, TEST FREQUENCY**  
CFR(s): 494.40(a)

6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours. Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet. Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L]. Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.

This STANDARD is not met as evidenced by:  
Based on review of the facility policy, facility Log Readings Report for Total Chlorine (TCL) documentation, and interview, it was determined staff failed to follow the facility policy to perform and document total chlorine testing at least every 4 hours while patients dialyzed. This had the potential to negatively affect all patients who are dialyzed at the facility. Findings include: Facility Policy: Carbon Filtration Monitoring for Incenter Central Water Systems Policy Reference Number: 46310 Version: 9 Published: 11/07/2022 Purpose of this policy is to provide instructions to... staff on carbon filtration monitoring of central water systems in Incenter facilities. Test Rationale...Total chlorine testing will be the only testing methodology used to ensure the carbon filters are reducing total chlorine levels below...0.10 ppm (parts per million)...testing for both free chlorine and chloramines. What to Test... Worker Carbon Filter... When to Test... Prior to the initiation of the first patient treatment of the day and at a minimum of every four hours... Routine Total Chlorine Testing will

be documented in the approved electronic documentation system... 1. Review of the facility Log Readings Report for TCL documentation dated 4/3/23 revealed the Patient Care Technician tested the chlorine at 7:55 AM and not again until 12:16 PM which was 4 hours 21 minutes and not every 4 hours per policy. In an interview conducted on 4/20/23 at 9:48 AM, Employee Identifier # 11, Biomedical Technician, confirmed staff failed to perform chlorine tests at least every 4 hours.

**V0250**

**DIALYS PROPOR-T-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, manufacturer's instructions for use for the Myron L D-6 Meter, and interviews, it was determined the facility failed to ensure staff rinsed the Myron L D-6 Meter with clean water after dialysate testing. This affected two of two observations of preparation of the hemodialysis (HD) machine prior to treatment initiation and had the potential to negatively affect all patients who dialyze at the facility. Findings include: Myron L Company Digital Dialysate Meter Operation Manual 16 February 16 page 11 ...VI. After Using the Dialysate Meter A. Maintenance of the Conductivity Cell Rinse out the conductivity cell with clean water... 1. An observation was conducted on 4/18/23 at 10:03 AM with EI (Employee Identifier) # 6, CCHT (Certified Clinical Hemodialysis Technician), and EI # 4, RN (Registered Nurse) to observe conductivity and pH (potential of hydrogen) testing using the Myron L D-6 Meter at station 11. EI # 6 tested the dialysate, read the conductivity results 13.7, pH 6.9, and EI # 4 verified the results. EI # 6 discarded the dialysate solution into the dirty sink and EI # 6 and EI # 4 exited the testing station. EI # 6 failed to rinse the Myron L meter with clean water after use per manufacturer's directions. There was no clean water at the dirty sink. An interview was conducted on 4/18/23 at 10:40 AM with EI # 1, Director of Operations, who confirmed staff failed to follow the Myron L meter directions for dialysate testing. 41624 2. An observation was conducted on 4/18/23 at 11:31 AM with EI # 5, CCHT, and EI # 4, RN to observe conductivity and pH testing using the Myron L D-6 Meter at station 15. EI # 5 tested the dialysate, read the conductivity results 13.8, pH 7.0, and verified by EI # 4. EI # 5 discarded the dialysate solution into the dirty sink and EI # 5 and EI # 4 exited the testing station. EI # 5 failed to rinse the Myron L meter with clean water after use per manufacturer's directions. There was no clean water at the dirty sink. An interview was conducted on 4/18/23 at 10:40 AM with EI # 1 who confirmed staff failed to follow the Myron L meter directions for use for dialysate testing.

**V0401**

**PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT**  
CFR(s): 494.60

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

This STANDARD is not met as evidenced by:

Based on observations, and interview, it was determined the facility failed to maintain dialysis treatment chairs to ensure effective disinfection between patients, and treatment chair function and comfort. This affected six of thirty patient treatment chairs and had the potential to negatively affect all patients who dialyze at the facility. Findings include: 1. During observations of care on 4/18/23 at 3:50 PM, tears/holes in the vinyl and excessive wear on the patient treatment chairs were identified below: a. station 11 treatment chair had a two 2 inch (in) L (length) x (by) one and one half in W (wide) tear with a gaping hole in the vinyl of the middle cushion in the footrest. b. station 20 treatment chair right arm rest had a one in L x one quarter in W tear in the vinyl and indentations in the seat cushion. c. station 18 treatment chair seat cushion had a one and one half in L x one quarter in W tear in the vinyl. d. station 7 treatment chair right arm rest had a one half inch L x one quarter in W tear in the vinyl and the left arm rest had a one and a half in L by one and a half in W tear in the vinyl. e. station 3 treatment chair seat cushion had a two in L by one quarter in W tear in the vinyl. f. station 26 treatment chair seat cushion had two tears in the vinyl measuring two in L x one quarter in W and one in L x one eighth in W. The patient treatment chairs had excessive wear which affected the function and comfort of the patient and the ability to adequately disinfect the chairs. An interview conducted was conducted on 4/20/23 at 10:40 AM with Employee Identifier # 2, Director of Operations, who confirmed the facility failed to maintain the patient treatment chairs.

**V0403**

PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU  
CFR(s): 494.60(b)

The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

This STANDARD is not met as evidenced by:  
Based on observations, manufacturer's directions for use for Minncare HD (hemodialysis) Residual Test Strips, and staff interviews, it was determined the facility failed to ensure: 1. Minncare HD Residual Test Strips located in the water room and available for use were not expired. 2. Supplies located in the Home Hemodialysis (HHD) and the Home Peritoneal Dialysis (HPD) rooms and available for use were not expired. Findings include: Mar Cor Publication A Cantel Medical Company Date: 2016 Minncare HD Test Strips Minncare HD test strips provide quick results with easy-to-read indicators with the assurance of accurate results associated with a 510 medical device. Use the Minncare HD ...Test strips as a pass/fail measurement for adequate concentration of sterilant after dilution... Both Minncare HD 1% Indicator Test Strips and Minncare HD Residual Test Strips may be used up to and including the last day of the month indicated by the expiration printed on the container... A tour of the water treatment room was conducted on 4/18/23 at 8:15 AM. A single opened vial of Minncare HD Residual Test Strips was observed available for use with an expiration date of 2/15/23. Employee Identifier (EI) # 13, Administrative Assistant, was present during the tour and confirmed the test strips were expired. 40119 2. A tour was conducted on 4/18/23 at 10:50 AM of the HPD storage room. The following supplies were expired and available for patient use: a. 141 Green topped blood collection tubes with the expiration date of 12/31/22. b. 21 Lime green topped blood collection tubes with the expiration date of 1/31/23. c. 65 Safety lancets 21 Gauge (G) with the expiration date of 11/23/22. d. 55 Safety-Lok 1 ml (milliliter) 25 G syringes with the expiration date of 10/19. e. One NxStage (Home HD machine

brand) conductivity preventive maintenance kit with the expiration date of 5/8/19. f. One Intravenous (IV) administration set with the expiration date of 8/7/22. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1, Director of Operations, who confirmed the supplies were expired and should not be available for patient use.

3. A tour was conducted on 4/18/23 at 11:39 AM of the HHD room. The following supplies were expired and available for patient use: a. One sterile 2 x 2 (two by two) gauze with the expiration date of 10/22. b. Four sterile 2 x 2 gauze with the expiration date of 11/22. c. Two sterile 2 x 2 gauze with the expiration date of 2/23. d. 23 RPC (brand of testing supplies) E-Z (easy) Check Blood Leak test strips with the expiration date of 1/31/19. e. One express fluid warmer disposable set with the expiration of 11/8/22. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1 who confirmed the supplies were expired and should not be available for patient use.

4. A tour was conducted on 4/20/23 at 12:50 PM of the HPD room. The following supplies were expired and available for patient use: a. 14 yellow topped blood collection tubes with the expiration date of 2/28/23. b. 17 red topped blood collection tubes with the expiration date of 2/8/23. c. 20 Stay safe cap PD connectology system with the expiration date of 1/31/23. d. 1 Exsept Plus (wound cleanser) 500 ml opened on 9/30/22 with an expiration date of 3/30/23. e. 2 sterile 2 x 2 gauze with the expiration date of 6/21. f. 2 sterile 2 x 2 gauze with the expiration date of 11/22. g. 39 Island 4 x 4 (four by four) dressings with the expiration date of 11/14/22. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1 who confirmed the supplies were expired and should not be available for patient use.

**V0407**

**PE-HD PTS IN VIEW DURING TREATMENTS**  
 CFR(s): 494.60(c)(4)

Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).

This STANDARD is not met as evidenced by:  
 Based on observations, facility policy, and interview, it was determined the staff failed to ensure all access sites were visible during dialysis treatments. This affected Patient Identifier (PI) # 20, one of one patient dialyzing in the isolation unit, and had the potential to negatively affect all patients who dialyzed by this facility. Findings include: Facility Policy: Patient Monitoring and Safety checks During Hemodialysis (HD) Treatment Policy Number: 23502 Version 4 Policy: Patient monitoring and safety check guidelines: Note: All patients must be under continual observation... Safety Check Access: Safety Checks include: Ensure each patient's face and access are uncovered... Ensure all patient connections are ALWAYS secure and uncovered due to serious risk of exsanguinations that could go undetected if the access was covered... 1. An observation of care in the isolation room for PI # 20 was conducted on 4/23/23 at 8:39 AM. The surveyor observed PI # 20's vascular assess site was covered with a blanket. During the observation Employee Identifier (EI) # 7, Certified Clinical Hemodialysis Technician (CCHT) entered the isolation room at 8:42 AM, then exited at 8:47 AM. The access site remained covered. EI # 7 entered the room again at 9:15 AM to perform vital signs, and PI # 20 was observed uncovering the access site himself/herself to have the blood pressure cuff applied. The access site was covered from 8:39 AM to 9:15 AM, a total of 36 minutes. EI # 7 failed to instruct the patient to uncover the access site when he/she entered at 8:42 AM. An interview was conducted on 4/20/23 at 10:50 AM with EI # 1, Director of Operations who confirmed access sites should always remain visible.

**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 algorithm, 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 543, V 544, 545, and V 559.

**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 review of medical records (MR), facility policies, facility "Recommended Volume Evaluation and Management Algorithm Version 2.0", and interviews with the staff, it was determined the facility failed to ensure: 1. The physician was notified of the patient leaving greater than 1.0 kg (kilograms) over the EDW (Estimated Dry Weight). 2. Normal Saline (NS) used for prime and post treatment rinse was documented. 3. Staff notified the nurse/physician with elevated BP (blood pressures) and administered ordered prn (as needed) Clonidine. This deficient practice affected six of seven in-center hemodialysis records reviewed and did affect Patient Identifier (PI) # 8, PI # 9, PI # 10, PI # 2, PI # 4, PI # 3, and had the potential to negatively affect all patients dialyzing at this facility. Findings include: Recommended Volume Evaluation and Management Algorithm Version 2.0 Date: 2019 Goal: Patient's post treatment will be less than 1 kg from EDW without signs or symptoms of hypervolemia or hypovolemia. ...6. EDW Assessment ...No sign or symptoms of hyper/hypovolemia... consult physician for new EDW. Facility Policy: Patient Assessment and Monitoring Published: 09/29/18 Version 3 Pre-Treatment Assessment and Data Collection Pre-Treatment: Direct patient care staff may collect pre-treatment weight, BP (blood pressure), pulse, respirations, temperature, general observations, access, and complaints reported by the patient. ...any changes or abnormal findings in patient's condition or vascular access are observed...the patient care technician (PCT) MUST report the changes in the patient condition to a registered nurse who will further assess the patient prior to initiation of the treatment. An abnormal finding confirmed by the RN (Registered Nurse) will be reported to the attending physician for assessment and intervention if necessary... During Treatment The RN will assess /re-assess any findings addressed pre or during treatment as needed... Follow the steps below for obtaining pre-treatment assessment data: 1. The direct care staff may obtain the following data: Weight: Record pre-weight. Compare pre-weight to estimated dry weight. Post-Treatment: ...The staff member who collects the information and evaluates the patient post-treatment will document their findings on the hemodialysis treatment record... any changes or abnormal findings in the patient's condition, vital signs or vascular access are observed...must report the changes in the patient condition to a RN who will further assess the patient prior to discharge... An abnormal finding confirmed by the RN will be reported to the attending physician... Monitoring During

Treatment ...Record BP...to the nurse: Systolic BP's greater than 180 mm/Hg (millimeters/mercury) Diastolic BP greater than 100 mm/Hg... Post-Treatment Follow the steps below for obtaining post-treatment assessment data: 1. The direct care staff may obtain the following data: Assessment and Data Collection Weight: obtain the patient's post weight. Ensure the post weight is consistent with the goals set of the machine... Facility Policy: Initiation of Treatment Using an Arteriovenous Graft or Fistula and Optiflux Single Use Ebeam Dialyzer. Published: 7/6/21 Version 5 Prior to Initiation: Assessment and Treatment Parameters. Follow the steps below to assess the patient, calculate the UF (ultrafiltration) goal and enter the prescribed treatment parameters: ...6. Add any fluids to be given during the treatment such as, saline prime /rinse back...during treatment... 1. PI # 8 was admitted to the facility on 9/14/2020 with a diagnosis of End Stage Renal Disease (ESRD). Review of the Treatment Sheet (TS) dated 4/14/23 revealed there was no documentation of the NS amount used for the rinse back at the end of the treatment. An interview was conducted on 4/19/23 at 11:27 AM with Employee Identifier (EI) # 2, Director of Operations (DOO), Sister Facility, who confirmed the staff failed to document the amount of NS used for rinse back at the end of treatment. 2. PI # 9 was admitted to the facility on 5/3/22 with diagnoses including ESRD. Review of the Order Summary Report (OSR) revealed Hemodialysis (HD) orders dated 2/9/23 which included EDW 115 kg. Review of the TS dated 4/6/23 revealed a pre-treatment weight of 125.0 kg and a post-treatment weight of 122.0 kg, which was 7.0 kg above the EDW. There was no documentation the physician was notified of the patient's post-treatment weight 7.0 kg above the ordered EDW. Review of the TS dated 4/8/23 revealed a pre-treatment weight of 119.7 kg and a post-treatment weight of 117.2 kg, which was 2.2 kg above the EDW. There was no documentation the physician was notified of the patient's post-treatment weight 2.2 kg above the ordered EDW. Review of the TS dated 4/11/23 revealed a pre-treatment weight of 123.3 kg and a post-treatment weight of 120.0 kg, which was 5.0 kg above the EDW. There was no documentation the physician was notified of the patient's post-treatment weight 5.0 kg above the ordered EDW. Review of the TS dated 4/13/23 revealed a pre-treatment weight of 125.0 kg and a post-treatment weight of 121.0 kg, which was 6.0 kg above the EDW. There was no documentation the physician was notified of the patient's post-treatment weight 6.0 kg above the ordered EDW. Review of the TS dated 4/15/23 revealed a pre-treatment weight of 120.7 kg and a post-treatment weight of 117.0 kg, which was 2.0 kg above the EDW. There was no documentation the physician was notified of the patient's post-treatment weight 2.0 kg above the ordered EDW. Review of the TS dated 4/18/23 revealed a pre-treatment weight of 124.6 kg and a post-treatment weight of 121.4 kg, which was 6.4 kg above the EDW. There was no documentation the physician was notified of the patient's post-treatment weight 6.4 kg above the ordered EDW. An interview was conducted on 4/19/23 at 3:15 PM with EI # 2 who confirmed there was no documentation the physician was notified of the patient post-treatment weights above the ordered EDW on 4/6/23, 4/8/23, 4/11/23, 4/13/23, 4/15/23 and 4/18/23. 3. PI # 10 was admitted to the facility on 8/6/2020 with diagnoses including ESRD. Review of the TS dated 4/13/23 revealed no documentation of the NS amount used for the prime administration at the beginning of the treatment. An interview was conducted on 4/19/23 at 11:27 AM with EI # 2 who confirmed the staff failed to document the amount of NS used for prime administration at the beginning of treatment. 41624 4. PI # 2 was admitted to the facility on 1/6/23 with a diagnosis of ESRD. Review of the TS dated 4/12/23 revealed no documentation of the NS amount used for the rinse back at the end of the treatment. An interview was conducted on 4/20/23 at 10:00 AM with EI # 1 who confirmed the staff failed to document the amount of NS used for rinse back at the end of treatment. 30952 5. PI # 4 was admitted to the facility on 12/27/22 with a diagnosis of ESRD. Review of the OSR revealed treatment medications included

Clonidine HCL (Hydrochloride) (for treatment of elevated BP) 0.2 mg (milligram) oral prn, start date 1/12/23. Review of the TS dated 4/11/23 revealed the nurse documented the pre-treatment BP sitting 143/81 at 11:10 AM. Further review of the 4/11/23 TS revealed the PCT documented the following elevated BP's: At 11:37 AM BP 173/104 At 12:03 PM BP 170/103 At 12:35 PM BP 180/110 At 1:42 PM BP 160/101 At 2:00 PM BP 171/100 There was no documentation the staff notified the nurse when the diastolic BP was greater than 100 mg/Hg. There was no documentation prn Clonidine was administered when the diastolic BP was greater than 100 from 11:37 AM until 2:00 PM. Review of the TS dated 4/15/23 revealed the nurse documented at 10:02 AM the pre-treatment BP sitting 212/127, at 10:14 AM treatment start time BP 221/123, at 10:33 AM BP 218/123, and 11:02 AM BP 198/117, which was greater than 180 systolic and 100 diastolic. There was no documentation the physician was notified of the BP's above 180 systolic and 100 diastolic. There was no documentation the nurse offered and administered prn Clonidine. Further review of the 4/15/23 TS revealed at 11:33 AM the PCT documented BP 180/110, and at 12:05 PM the BP was 179/106. There was no documentation staff notified the nurse the diastolic BP was greater than 100. An interview was conducted on 4/19/23 at 2:45 PM with EI # 2, who confirmed the staff failed to notify the nurse/physician of systolic BP greater than 180 and diastolic greater than BP 100. There was no documentation prn Clonidine was offered/administered. 6. PI # 3 was admitted to the facility on 11/29/19 with diagnoses including ESRD. Review of the TS dated 4/14/23 revealed no documentation of the NS amount used for the rinse back at the end of the treatment. An interview was conducted on 4/19/23 at 3:53 PM with EI # 1, who confirmed the staff failed to document the amount of NS used for rinse back at the end of treatment.

**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, it was determined the facility failed to ensure: 1. The staff followed the physician's orders for Blood Flow Rate (BFR) and/or Dialysate Flow Rate (DFR). 2. The patient documented the number and amount of exchanges on the PD (Peritoneal Dialysis) treatment record. This affected six of seven in-center hemodialysis records reviewed including Patient Identifier (PI) # 8, PI # 9, PI # 10, PI # 2, PI # 1, PI # 3, and one of two home PD records reviewed, including PI # 7. This had the potential to negatively affect all patients dialyzing at the facility. Findings include: Facility Policy: Patient Assessment and Monitoring Published: 09/29/18 Version: 3 Monitoring During Treatment 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 ... Check dialysate flow rate setting is correct, and the prescribed flow is being delivered ... 4. Document any findings and interventions in the medical record. Facility Policy: Home Therapies Patient Treatment Record Keeping Published: 11/2/2020 Version: 1 Purpose: The purpose of this policy is to provide guidance for documentation of dialysis treatments for home dialysis patients. Background: The treatment flowsheet is used to monitor patient...aspects of treatment...and compliance with treatment regimen... Policy: A record is required for each dialysis treatment. Patients and/or patient care partners will be taught to

complete a daily record of home dialysis treatments and...educated regarding the importance of maintaining the records completely and accurately. ...Home treatment records will be reviewed by the home therapy registered nurse during patient monthly clinic visits to identify trends, errors or omissions, and other issues or concerns to be addressed with the patient and/or care partner...

1. PI # 8 was admitted to the facility on 9/14/2020 with diagnoses including End Stage Renal Disease (ESRD). Review of the Order Summary Report (OSR) revealed Hemodialysis (HD) orders dated 3/27/23 which included BFR 400 and DFR Autoflow 1.5 (600). Review of the Treatment Sheet (TS) dated 4/5/23 revealed the BFR was decreased to 300 from 10:31 AM to 11:30 AM and from 11:59 AM to 1:56 PM. There was no reason documented why the BFR was 300 and not 400 as ordered. Review of the TS dated 4/17/23 revealed the DFR was 800 the entire treatment from 10:20 AM to 2:14 PM. There was no reason documented why the DFR was 800 and not 600 as ordered. An interview was conducted on 4/19/23 at 11:27 AM with Employee Identifier (EI) # 2, Director of Operations (DO), Sister Facility, who verified the staff failed to document the reason the BFR was not delivered as ordered and failed to administer the DFR per physician orders.

2. PI # 9 was admitted to the facility on 5/3/22 with diagnoses including ESRD. Review of the OSR revealed HD orders dated 2/9/23 which included BFR 450 and DFR Autoflow 1.5 (700). Review of the TS dated 4/6/23 revealed the BFR was 400 and DFR was 600 the entire treatment from 5:34 AM to 9:52 AM. There was no reason documented why the BFR was 400 and not 450 as ordered and the DFR was 600 and not 700 as ordered. Review of the TS dated 4/8/23 revealed the treatment was initiated at 5:40 AM and there was no documentation of BFR and DFR until 6:01 AM. The staff failed to administer the BFR 450 and DFR 700 per the physician's order upon initiation of treatment at 5:40 AM. Further review of the TS dated 4/8/23 revealed the BFR was 400 from 6:01 AM to 8:11 AM, then the BFR was decreased to 170 and the DFR decreased to 140 from 8:11 AM to 8:31 AM, at which time the BFR was increased to 400 until the end of treatment at 10:09 AM. There was no reason documented why the BFR was 170 and 400 and not 450 as ordered and the DFR was 140 and not 700 as ordered. Review of TS dated 4/11/23 revealed the BFR was 400 from 5:45 AM to 6:00 AM and from 6:34 AM until the end of treatment at 10:33 AM. The DFR was at 800 the entire treatment from 5:45 AM until 10:33 AM. There was no reason documented why the BFR was 400 and not 450 as ordered and the DFR was 800 and not 700 as ordered. Review of TS dated 4/13/23 revealed the DFR was 800 the entire treatment from 5:48 AM until 10:18 AM. There was no reason documented why the DFR was 800 and not 700 as ordered. Review of TS dated 4/15/23 revealed the DFR was 800 the entire treatment from 5:38 AM until 10:13 AM. There was no reason documented why the DFR was 800 and not 700 as ordered. Review of the TS dated 4/18/23 revealed the treatment was initiated at 5:40 AM with a DFR of 500. At 6:05 AM, the DFR was increased to 800. At 6:38 AM, the DFR was decreased to 500, and then from 7:01 AM until 8:00 AM, the DFR was increased to 800, at which time the DFR was decreased to 500 until 8:41 AM. There was no reason documented why the DFR was 500 and 800 and not 700 as ordered. An interview was conducted on 4/19/23 at 3:15 PM with EI # 2, who verified the staff failed to document the reason the BFR was not delivered as ordered and failed to administer the DFR per physician orders.

3. PI # 10 was admitted to the facility on 8/6/2020 with diagnoses including ESRD. Review of the OSR revealed HD orders dated 1/26/23 which included BFR 400 and DFR Manual 500. Review of the TS dated 4/11/23 revealed the DFR was increased to 800 from 10:32 AM to 11:30 AM. There was no reason documented why the DFR was 800 and not 500 as ordered. Review of the TS dated 4/13/23 revealed the DFR was 800 the entire treatment from 10:06 AM to 2:08 PM and the BFR was decreased to 300 from 12:41 PM to 2:08 PM. There was no reason documented why the DFR was 800 and not 500 as ordered and the BFR was

300 and not 400 as ordered. An interview was conducted on 4/19/23 at 2:45 PM with EI # 2, who verified the staff failed to document the reason the BFR was not delivered as ordered and failed to administer the DFR per physician orders. 41624 4. PI # 2 was admitted to the facility on 1/6/23 with a diagnosis of ESRD. Review of the OSR revealed HD orders dated 2/24/23 which included BFR 400. Review of the TS dated 4/14/23 revealed the BFR was decreased to 350 from 1:32 PM to end of treatment at 2:43 PM. There was no documentation why the BFR was not at the ordered rate of 400. Review of the TS dated 4/17/23 revealed the BFR was 350 at start of treatment 10:40 AM to 11:02 AM, and from 12:02 PM to 1:31 PM the BFR was 350. Further review of the 4/17/23 TS revealed from 1:31 PM to 2:03 PM the BFR was 300 and from 2:03 PM to 2:35 PM the BFR was 350. There was no documentation why the BFR was not at the ordered rate of 400. An interview was conducted on 4/20/23 at 10:00 AM with EI # 1, Director of Operations, who confirmed there was no documentation why the BFR was not 400 as ordered. 5. PI # 1 was admitted to the facility on 3/4/23 with a diagnosis of ESRD. Review of the OSR revealed HD orders dated 3/4/23 which included BFR 400. Review of the TS dated 4/4/23 revealed the BFR was 350 from start of treatment 11:05 AM to 1:02 PM and the BFR was 300 from 1:02 PM to end of treatment 3:09 PM. There was no documentation why the BFR was not 400 as ordered. Review of the TS dated 4/15/23 revealed the BFR was 250 from start of treatment 11:11 AM to end of treatment 2:39 PM. There was no documentation why the BFR was not 400 as ordered. Review of the TS dated 4/18/23 revealed BFR was decreased to 300 at 12:33 PM until end of treatment 3:11 PM. There was no documentation why the BFR was not at the ordered rate of 400. An interview was conducted on 4/20/23 at 9:40 AM with EI # 1 who confirmed there was no documentation why the BFR was not 400 as ordered. 30952 6. PI # 3 was admitted to the facility on 11/29/19 with diagnoses including ESRD. Review of the OSR revealed HD orders dated 4/7/23 which included BFR 525 and DFR Autoflow 2.0 (800). Review of the TS dated 4/7/23 revealed the DFR was 600 from treatment start at 6:05 AM to 9:02. Further review of the 4/7/23 TS revealed the BFR was 300 from 6:46 AM until 9:02 AM. There was no reason documented why the DFR was 600 and not 800 as ordered and the BFR was 300 and not 525 as ordered. Review of the TS dated 4/12/23 revealed the BFR was 400 from 6:32 AM until 9:55 AM, treatment termination. There was no reason documented why the BFR was not 525 as ordered. An interview was conducted on 4/19/23 at 3:53 PM with EI # 1 who confirmed the staff failed to document the reason the BFR was not delivered as ordered and failed to administer the DFR per physician orders. 40119 7. PI # 7 was admitted to the facility on 2/14/22 with a diagnosis of ESRD. Review of the OSR revealed an order for PD dated 7/16/22 for CCPD (Continuous Cyclic Peritoneal Dialysis, which requires the use of a Cycler) seven days a week, five exchanges in which four would be with 2000 ml (milliliters) and the last exchange would be with 1000 ml. The average dwell time ordered at one hour and 40 minutes and the cyclic therapy time of eight hours and 30 minutes with an EDW of 71.5 kg. Review of the Treatment Summary PD revealed documentation of daily treatments from 2/19/23 to 4/2/23. Further review revealed documentation of 2000 (milliliters) under Dextrose 2.5 %. There was no documentation of the daily total number and amount of each exchange on the home treatment record. Review of the Home PD Nurse TS Monthly Check Off dated 3/15/23 and 4/3/23 revealed no documentation the patient was educated on documenting the daily total number and amount of each exchange on the home treatment record. In an interview conducted on 4/19/23 at 3:00 PM, EI # 10, Home PD Nurse, confirmed the 2000 ml amount was for one exchange and the daily total number and the amount of each exchange was not documented on the home treatment record. In an interview conducted on 4/20/23 at 8:45 AM, EI # 2, Director of Operations, Sister Facility, confirmed there was no documentation of the daily total number and amount of each

exchange on the home treatment record from 2/19/23 to 4/2/23.

**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 review of medical records (MR) and interview, it was determined the facility failed to ensure all oral nutritional supplements were given as ordered per the physician orders. This affected one of five in-center hemodialysis patients receiving oral nutritional supplements and did affect Patient Identifier (PI) # 8 and had the potential to negatively affect all patients served by the facility. Findings include: 1. PI # 8 was admitted to the facility on 9/14/2020 with diagnoses including End Stage Renal Disease. Review of the Order Summary Report dated 9/21/22 revealed an order as follows: "LiquaCel - 1 oz (ounce) po (by mouth) during dialysis 3 x (times) week". Review of the Treatment Sheets dated 4/5/23, 4/12/23, and 4/17/23 revealed no documentation the LiquaCel was administered as ordered. An interview was conducted on 4/19/23 at 11:27 AM with Employee Identifier # 2, Director of Operations, Sister Facility who confirmed the staff failed to administer LiquaCel as ordered.

**V0559**

**POC-OUTCOME NOT ACHIEVED-ADJUST POC**

CFR(s): 494.90(b)(3)

If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must- (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.

This STANDARD is not met as evidenced by:

Based on review of medical records (MR), facility policy and staff interview the interdisciplinary (IDT) team failed to adjust the plan of care to reflect the patient's current condition. This deficient practice affected Patient Identifier (PI) # 5 and PI # 7, two of two Peritoneal Dialysis (PD) records reviewed, and had the potential to affect all PD patients served by the facility. Findings include: Facility Policy: Comprehensive Interdisciplinary Assessment and Plan of Care (POC) Version Number: 5 Published Date: 4/24/19 Purpose: The purpose of this policy is to provide guidance on the requirements for the Comprehensive Interdisciplinary Assessment (CIA) and the patient POC. ...Comprehensive Assessment Participation...The following are recommendations that may be used for the interdisciplinary patient assessment, development, and review of the POC prior to implementation: ...Plan of care discussions may occur during rounds... Failure to Achieve POC Outcome If the patient specific expected outcome as determined by the attending physician, IDT, and patient for the POC is not achieved within the identified timeframe: The IDT must adjust the patient's POC, and document changes made to the POC. Implement the

POC changes to address the identified issues... 1. PI # 5 was admitted to the facility on 2/3/22 with a diagnosis of End Stage Renal Disease (ESRD). Review of the OSR (Orders Summary Report) revealed an order for PD dated 11/29/22 with an Estimated Dry Weight (EDW) of 68 kg (kilograms). Review of the POC dated 12/13/22 revealed documentation of the following: a. A goal to maintain/achieve desired body weight with an intervention to monitor weight goal progress updated on 12/9/22 by the dietician. b. A goal to maintain the iPTH (Intact Parathyroid Hormone) between 160 and 720 pg/ml (picograms per milliliter) with interventions of monitoring the iPTH and continue Sensipar per physician orders updated on 12/9/23 by the dietician. Review of the Provider Round Note dated 12/13/22, 3/14/23 and 4/18/23 revealed documentation to decrease the DW (dry weight) from 68 kg to 66 kg. Review of the PD Treatment Summary dated from 2/19/23 to 4/17/23 revealed the following treatments and weights were documented: On 3/8/23, completed treatment with a weight of 60 kg. On 3/9/23, completed treatment with a weight of 61 kg. On 3/10/23, completed treatment with a weight of 58.9 kg, which was the lowest documented weight for PI # 5. On 3/11/23, completed treatment with a weight of 59.7 kg. On 3/12/23, completed treatment with a weight of 60 kg. On 4/1/23, completed treatment with a weight of 63.8 kg. On 4/2/23, completed treatment with a weight of 63.7 kg. On 4/3/23, completed treatment with a weight of 63.9 kg. On 4/4/23, completed treatment with a weight of 63.8 kg. On 4/5/23, completed treatment with a weight of 64 kg. On 4/6/23, completed treatment with a weight of 63.8 kg. On 4/7/23, completed treatment with a weight of 63.7 kg. On 4/8/23, completed treatment with a weight of 63.9 kg. On 4/9/23, completed treatment with a weight of 64.2 kg. On 4/10/23, completed treatment with a weight of 63.8 kg. On 4/11/23, completed treatment with a weight of 63.7 kg. On 4/12/23, completed treatment with a weight of 64.1 kg. On 4/13/23, completed treatment with a weight of 64.2 kg, which was the highest documented weight for PI # 5. On 4/14/23, completed treatment with a weight of 63.9 kg. On 4/15/23 and 4/16/23, completed treatment with a weight of 63.8 kg. On 4/17/23, completed treatment with a weight of 64 kg. Further review of the Provider Round Notes dated 3/14/23 and 4/18/23 revealed documentation to increase Sensipar to 60 mg (milligram) a day in response to an iPTH of 1235 on 3/9/23 and a iPTH of 1453 on 4/10/23. Review of the MR revealed no documentation PI # 5's POC was adjusted to reflect the provider's decrease of the DW from 68 kg to 66 kg and to increase Sensipar to 60 mg a day. In an interview conducted on 4/20/23 at 8:53 AM, Employee Identifier (EI) # 2, Director of Operations, Sister Facility, confirmed there was no documentation PI # 5's POC was adjusted to reflect the provider's decrease of the DW from 68 kg to 66 kg and to increase Sensipar to 60 mg a day. 2. PI # 7 was admitted to the facility on 2/14/22 with a diagnosis of ESRD. Review of the OSR revealed an order for PD dated 7/16/22 for CCPD (Continuous Cyclic Peritoneal Dialysis, which requires the use of a Cycler) seven days a week, five exchanges in which four would be with 2000 ml (milliliters) and the last exchange would be with 1000 ml. The average dwell time ordered at one hour and 40 minutes and the cyclic therapy time of eight hours and 30 minutes with an EDW of 71.5 kg. Further review of the OSR revealed no documentation of a physician's order for CAPD (Continuous Ambulatory Peritoneal Dialysis, which does not require the use of a cyclor and is a "manual" PD) Review of the Provider Round Note dated 12/13/22, 3/21/23 and 4/11/23 revealed documentation to decrease the DW to 70 kg. Review of PI # 7's POC dated 2/14/23 revealed documentation of the following: a. A goal to maintain/achieve desired body weight with an intervention to monitor weight goal progress updated on 1/31/23 by the dietician. b. A goal to improve treatment adherence with an intervention to continue to monitor the patient since the "patient is adherent to treatment..." Review of the PD Treatment Summary dated from 2/19/23 to 4/2/23 revealed the following treatments and weights were documented: On 2/19/23, completed CAPD treatment

with a weight of 73.83 kg. On 2/20/23, completed CAPD treatment with a weight of 73.06 kg. On 2/21/23, 2/22/23, 2/23/23 and 2/24/23, completed CAPD treatment with a weight of 72.11 kg. On 2/25/23, completed CAPD treatment with a weight of 71.38 kg. On 2/26/23, completed CAPD treatment with a weight of 72.11 kg. On 2/27/23 and 2/28/23, completed CAPD treatment with a weight of 73.2 kg. On 3/1/23, completed CAPD treatment with a weight of 73.56 kg. On 3/2/23, completed CAPD treatment with a weight of 73.65 kg. On 3/3/23, completed CAPD treatment with a weight of 74.06 kg. On 3/4/23, completed CAPD treatment with a weight of 72.56 kg. On 3/5/23, completed CAPD treatment with a weight of 71.66 kg. On 3/6/23 and 3/7/23, completed CAPD treatment with a weight of 71.11 kg. On 3/8/23, completed CAPD treatment with a weight of 70.29 kg. On 3/9/23, completed CAPD treatment with a weight of 69.93 kg, which was the lowest documented weight for PI # 7. On 3/10/23, completed CAPD treatment with a weight of 70.07 kg. On 3/11/23 and 3/12/23, completed CAPD treatment with a weight of 70.75 kg. On 3/13/23 and 3/14/23, completed CAPD treatment with a weight of 72.02 kg. On 3/15/23, completed CCPD treatment with a weight of 72.56 kg, which was the only date a CCPD treatment was completed. On 3/16/23, completed CAPD treatment with a weight of 72.29 kg. On 3/17/23 and 3/18/23, completed CAPD treatment with a weight of 72.74 kg. On 3/19/23, completed CAPD treatment with a weight of 73.02 kg. On 3/20/23 and 3/21/23, completed CAPD treatment with a weight of 74.2 kg. On 3/22/23, completed CAPD treatment with a weight of 74.06 kg. On 3/23/23 and 3/24/23, completed CAPD treatment with a weight of 78.0 kg, which was the highest documented weight for PI # 7. On 3/25/23, completed CAPD treatment with a weight of 77.1 kg. On 3/26/23, 3/27/23 and 3/28/23, completed CAPD treatment with a weight of 76.37 kg. On 3/29/23 and 3/30/23, completed CAPD treatment with a weight of 76.01 kg. On 3/31/23, completed CAPD treatment with a weight of 75.28 kg. On 4/1/23, completed CAPD treatment with a weight of 75.33 kg. On 4/2/23, completed CAPD treatment with a weight of 75.74 kg. Review of the MR revealed no documentation PI # 7's POC was adjusted to reflect the provider's decrease of the DW to 70 kg and the patient's nonadherence with the physician ordered CCPD treatments. In an interview conducted on 4/20/23 at 8:45 AM, EI # 2 confirmed there was no documentation PI # 7's POC was adjusted to reflect the provider's decrease of the DW to 70 kg, the patient's nonadherence with the physician ordered CCPD treatments and staff failed to adjust the POC to reflect the patient's current condition.

**V0681**

**PQ-STAFF LIC AS REQ/QUAL/DEMO COMPETENCY**  
CFR(s): 494.140

All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.

This STANDARD is not met as evidenced by:

Based on review of the ESRD (End Stage Renal Disease) Core Survey Facility Worksheet: Personnel File, employee personnel file, facility policy, and interview, it was determined the facility failed to ensure staff completed annual competencies for one of three CCHT (Certified Clinical Hemodialysis Technician) files reviewed, including EI (Employee Identifier) # 7, CCHT. This had the potential to affect all patients served by the facility. Findings include: Facility Policy: Knowledge, Skills

and Competency for Clinical Staff Published: 10/12/2021 Version: 3 Purpose ...FKC (Fresenius Kidney Care) provides all clinical field employees with initial and ongoing development and evaluation of the knowledge and skills essential for a highly functional and well-trained workforce. Background The following are...required clinical topics covered during training... -Initial, Annual, and One-time Role Specific Training -Initial, Annual, and One-time Role Specific Knowledge Evaluation -Initial, Annual, and One-time Role Specific Skills Evaluation ...Policy Employees are required to pass all exams, including an initial and annual exam. Employees are required to successfully complete all skills requirements, including an initial and annual skills validation, within the given timeframe. Employees without current documented competency within the past 365 days may be removed from performing independent direct patient care (DPC) until competency is demonstrated and documented. ...Documentation Completion dates are entered...for ... annual exam and skills validation...Annual Skills Validation.... A review of the 'ESRD Core Survey Facility Worksheet: Personnel File' dated 4/19/23 revealed EI # 7's, date of hire was 2/26/01 and Competencies Documented Dates were 12/23/23. On 4/20/23 at 8:50 AM a review of EI # 7's Education Transcript dated 4/18/2020 to 4/18/23 revealed the last Clinical Annual Competency Exam-Direct Patient Care completion date was 4/29/2020, the Annual Clinical Skills Validation and Exam for PCT (Patient Care Technician) completion date was 12/23/2020 . Further personnel documentation review revealed an Annual Direct Patient Care Skills Validation Checklist, Outpatient Hemodialysis, revealed EI # 7's last completed competency validation was 6/30/21, which was greater than 365 days. In addition, no Clinical Manager and Medical Director signature/date was documented on the 6/30/21 Annual Skills Validation Checklist. An interview was conducted on 4/20/23 at 10:40 AM with EI # 1, Director of Operations who confirmed staff failed to complete the competency skills evaluation within 365 days, per policy.