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	152647	A. BUILDING _____ B. WING _____	01/28/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FORT WAYNE SOUTH DIALYSIS	302 E PETTIT AVE FORT WAYNE, IN 46806

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
E 000	Initial Comments An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62. Survey Dates: January 25th, 26th, 27th, and 28th of 2022 At this Emergency Preparedness survey, Fort Wayne South Dialysis was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.	E 000		
V 000	INITIAL COMMENTS This visit was for a Federal ESRD (Core) recertification survey in conjunction with a COVID-19 focused infection control survey. Survey Dates: January 25th, 26th, 27th, and 28th of 2022. At this survey, Fort Wayne South Dialysis was found to be out of compliance with Conditions for Coverage 42 CFR 494.130 Laboratory Services and 42 CFR 494.40 Water and Dialysate Quality. An Immediate Jeopardy related to 42 CFR 494.130 Laboratory Services was identified and announced on Thursday, January 28, 2022, at 9:00 a.m. The facility's immediate jeopardy removal of immediacy plan and actions were determined to have removed the immediacy component on 1/28/2022 at the time of survey exit.	V 000		
V 113	IC-WEAR GLOVES/HAND HYGIENE CFR(s): 494.30(a)(1)	V 113		3/1/22

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 02/17/2022

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V 113	Continued From page 1	V 113		

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 observation, record review, and interview, the facility failed to ensure proper infection control practices were maintained in 1 of 2 AVF (arteriovenous fistula) observations. (Patient 12)

Findings Include:

1. A policy titled "Infection Control for Dialysis Facilities" dated October 2021 was provided by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to, "1. Hand hygiene is to be performed" ... "after contamination of blood or other infectious material" ... "before touching clean areas such as supplies" ... "Teammates will keep fingers, pens, pencils, labels, etc., away from mouth."

2. An observation was completed on Employee J on 1/26/2022 at 10:48 a.m. Employee J sanitized hands and applied clean gloves and initiated treatment on Patient 12 in station 12. Throughout the initiation of treatment, Employee J was observed adjusting his face mask on multiple occasions with gloved hands while cannulating (inserting needles into an access) Patient 12's access. No hand hygiene or glove changes were completed after adjusting face mask during the cannulation process.

3. An interview was completed with Employee A

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V 113	Continued From page 2 on 1/26/2022 at 2:15 p.m. Employee A was notified of staff member observed initiating dialysis for a patient and observed adjusting face mask with clean gloves on, never re-sanitizing hands or replacing gloves. Employee A indicated that she had an idea of what staff member surveyor was referring to and verbalized Employee J's name. No further information was provided.	V 113		
V 115	IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK CFR(s): 494.30(a)(1)(i) Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure patients were following infection control practices to prevent the spread of COVID-19 infection. Findings Include: 1. A document titled "CDC COVID-19" was obtained from the CDC website on 2/2/2022. The documented indicated but was not limited to, "Wear a mask: Everyone ages 2 years and older should properly wear a well-fitting mask indoors in public areas of substantial or high community transmission, regardless of vaccination status."	V 115		3/1/22

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V 115	Continued From page 3 2. A document titled "COVID-19 Information" was obtained from the DaVita website on 2/2/2022. The document indicated but was not limited to, "Frequently Asked Questions" ... "What can patients do to protect themselves?" ... "These are the actions you can take to stay safe. These include:" ... "While incenter, follow our infection control practices, such as wearing a mask." 3. During an observation on 1/26/2022 at 11:00 a.m. a patient located in station 13 was not wearing a mask during treatment. A patient in station 14 was observed wearing his mask below his chin during treatment. A patient in station 2 was observed with no mask on during treatment, and a patient in station 12 was observed with mask below chin during treatment. 4. An interview was completed with Employee A on 1/26/2022 at 11:00 a.m. Employee A was advised of patients observed on the treatment floor in stations 2, 12, 13, and 14 not wearing masks or improperly wearing masks during treatment. Employee A immediately reminded all patients to wear mask while in the facility. Patients immediately complied.	V 115		
V 117	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	V 117		3/1/22

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V 117	Continued From page 4	V 117		

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, record review, and interview, the facility failed to maintain the integrity of clean supplies and equipment in 1 or 2 observations.

Findings Include:

1. A policy titled "Infection Control for Dialysis Facilities" dated October 2021 was provided by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to, "Clean areas should be clearly designated for the preparation, handling, and storage of medications and clean supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled."

2. During an observation on 1/25/2022 at 11:00 a.m. a drawer located at the nurse's station contained a combination of clean supplies and personal items. Clean supplies: Multiple rolls of clean tape used on patient access sites (Fistulas, Grafts, & central venous catheters) and 2

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V 117	Continued From page 5 keyboard covers wrapped in plastic. Other items located in the same drawer included a winter hat, pencils, pens, a calculator, 2 television remotes, a pair of winter gloves, a flashlight, toenail clippers, and fingernail clippers. 3. During an interview with Employee J on 1/25/2022 at 11:00 a.m. Employee J indicated uncertainty as to how the clean supplies got into this drawer as this drawer had been designated as a lost and found drawer and/or a catch all drawer.	V 117		
V 122	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 observation, record review, and interview, the facility failed to ensure all staff demonstrated proper infection control procedures for cleaning and disinfection of contaminated surfaces to safeguard against potential transmission of COVID-19 during 2 of 2 observations on the treatment floor, with the potential to affect all patients. Findings Include:	V 122		3/1/22

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1. A policy titled "Infection Control for Dialysis Facilities" dated October 2021 was provided by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to, "25. Non-disposable items are to be disinfected between patients." ... "71. When cleaning the dialysis station post treatment, CDC recommendations and CMS regulations require the dialysis station be completely vacated by the previous patient before teammates can begin cleaning and disinfection of the station and set up for the next patient."

2. A CMS Memo QSO-20-20-ALL indicated, but was not limited to; "Transmission-Based Precautions ... Dedicated or disposable noncritical patient-care equipment (e.g., blood pressure cuffs, blood glucose monitor equipment) are used, or if not available, then equipment is cleaned and disinfected according to manufacturer's instructions using an EPA-registered disinfectant prior to use on another patient or before being returned to a common clean storage area ..."

3. During an observation on 1/25/2022 from 10:45 a.m. through 12:15 p.m. during patient turn-over from 1st shift patients to 2nd shift patients, the scale keypad and grab bar were not disinfected between any patients entering the treatment floor to begin treatment or patients exiting the treatment floor post treatment. A total of 20 dialysis chairs were in use.

4. During an observation on 1/26/2022 from 10:00 a.m. through 11:57 a.m. during patient turn-over from 1st shift patients to 2nd shift patients the scale keypad and grab bar were not disinfected between any patients entering the treatment floor

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V 122	Continued From page 7 to begin treatment or patients exiting the treatment floor post treatment. A total of 20 treatment were chairs in use. 5. A interview with Employee J was completed on 1/25/2022 at 12:32 p.m. Employee J indicated the scale keypad and grab bar does not get disinfected between each patient use, only between each patient shift. High touch areas like doorknobs and nurse and technician station counters are disinfected between each shift. Denied lobby chairs being disinfected between each shift, only disinfected nightly.	V 122		
V 175	CFC-WATER & DIALYSATE QUALITY CFR(s): 494.40 This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the facility failed to ensure chlorine testing for water was tested specific to the testing measures of the product supplied by the facility (See V0196); and facility failed to ensure the solution used to test for pH and conductivity was not expired (See V0250). The cumulative effect of this systemic problem resulted in the facility being out of compliance with 42 CFR 494.40 Water & Dialysate Quality.	V 175		3/1/22
V 196	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	V 196		3/1/22

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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 record review and interview, the facility failed to ensure that chlorine testing for water was tested specific to the testing measures of the product supplied by the facility in 1 of 1 facility.

Findings Include:

1. A policy titled "Daily Water System Total Chlorine Monitoring" dated March 2015 was provided by Employee A on 1/28/2022 at 4:10 p.m. The policy indicated but was not limited to, "Total Chlorine testing is done on a daily basis prior to the first patient treatment and every four

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(4) hours until all activities that require use of dialysis quality water are completed" ... "The following test kits/strips are approved for Total Chlorine testing of water used for dialysis in DaVita facilities: 1. RPC Ultra Low Total Chlorine Test Strip, SteriChek Total Chlorine Test Strips, E-Z Check Chloramine Test Strips, Serim Hisense 0.1 Test Strips."

2. A review of the total chlorine logs reviewed on 1/28/2022 from 10/16/2021 through 1/27/2022 evidenced the following manual readings:

10/16/2021 at 5:15 a.m. Result 0.01
10/18/2021 at 4:50 a.m. Result <0.02
10/19/2021 at 5:15 a.m. Result 0.03
10/20/2021 at 4:50 a.m. Result <0.02
10/22/2021 at 4:50 a.m. Result <0.02
10/25/2021 at 4:50 a.m. Result <0.02
10/26/2021 at 5:05 a.m. Result 0.02
10/27/2021 at 5:00 a.m. Result <0.01
10/30/2021 at 5:15 a.m. Result 0.01
11/1/2021 at 5:10 a.m. Result 0.02
11/3/2021 at 4:50 a.m. Result <0.02
11/5/2021 at 5:00 a.m. Result <0.02
11/6/2021 at 4:50 a.m. Result <0.02
11/7/2021 at 5:00 a.m. Result <0.02
11/8/2021 at 5:10 a.m. Result 0.02
11/9/2021 at 5:15 a.m. Result 0.01
11/15/2021 at 5:00 a.m. Result < 0.01
11/16/2021 at 5:14 a.m. Result 0.01
11/19/2021 at 4:45 a.m. Result 0.02
11/20/2021 at 4:50 a.m. Result <0.02
11/22/2021 at 4:50 a.m. Result <0.02
11/24/2021 at 4:40 a.m. Result <0.02
11/26/2021 at 5:00 a.m. Result <0.02
11/27/2021 at 5:15 a.m. Result 0.01
11/29/2021 at 5:16 a.m. Result 0.01
11/30/2021 at 5:12 a.m. Result 0.01

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12/13/2021 at 5:10 a.m. Result 0.01
12/17/2021 at 3:00 p.m. Result <0.01
12/17/2021 at 5:00 p.m. Result <0.01
12/18/2021 at 9:00 a.m. Result <0.01
12/18/2021 at 12:47 p.m. Result <0.01
12/18/2021 at 4:50 p.m. Result <0.01
12/20/2021 at 5:00 a.m. Result <0.01
12/20/2021 at 11:25 a.m. Result <0.01
12/20/2021 at 2:24 p.m. Result <0.01
12/20/2021 at 6:12 p.m. Result <0.01
12/21/2021 at 7:00 a.m. Result 0.01
12/23/2021 at 6:30 a.m. Result <0.01
12/23/2021 at 6:30 p.m. Result <0.01
12/26/2021 at 4:58 a.m. Result <0.01
12/26/2021 at 8:00 a.m. Result <0.01
12/27/2021 at 5:00 a.m. Result <0.01
12/27/2021 at 8:30 a.m. Result <0.01
12/27/2021 at 10:20 a.m. Result <0.01
12/27/2021 at 1:53 p.m. Result <0.01
12/27/2021 at 1:53 p.m. Result 0.01
12/27/2021 at 3:15 p.m. Result 0.01
12/28/2021 at 3:00 p.m. Result <0.01
12/28/2021 at 6:13 p.m. Result <0.01
12/27/2021 at 10:20 a.m. Result <0.01
12/30/2021 at 5:00 a.m. Result 0.01
12/30/2021 at 7:30 a.m. Result 0.01
12/30/2021 at 11:30 a.m. Result 0.01
12/31/2021 at 5:31 p.m. Result 0.01
12/30/2021 at 5:00 a.m. Result 0.01
1/2/2022 at 4:40 a.m. Result 0.01
1/1/2022 at 4:40 a.m. Result 0.01
1/4/2022 at 5:00 a.m. Result 0.01
1/4/2022 at 9:00 a.m. Result 0.01
1/5/2022 at 6:54 a.m. Result 0.01
1/7/2022 at 7:58 a.m. Result 0.01
1/10/2022 at 6:00 p.m. Result 0.01
1/11/2022 at 5:00 a.m. Result 0.01
1/17/2022 at 5:00 a.m. Result 0.01
1/19/2022 at 8:00 a.m. Result 0.01

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V 196	Continued From page 11 1/24/2022 at 5:14 a.m. Result 0.01 1/24/2022 at 8:00 a.m. Result 0.01 1/24/2022 at 11:19 a.m. Result 0.01 1/24/2022 at 3:00 p.m. Result 0.01 1/24/2022 at 6:30 p.m. Result 0.01 1/26/2022 at 11:30 a.m. Result 0.01 3. An interview was completed with Employee A on 1/28/2022 at 3:55 p.m. Employee A confirmed that automatic testing of chlorine levels was completed by the CM130 every 5 minutes, however, manual testing completed each morning by the opening staff members are to use the Serim Guardian HiSense Ultra 0.1 testing strips. Confirmed these testing strips can only differentiate between the values of 0.0 or <0.1. The values in between (0.01, 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.08, and 0.09) cannot be verified using the Serim Guardian HiSense Ultra 0.1 testing strips supplied to staff for use. Denied staff having access to testing strips in the facility that would differentiate the values of 0.1-0.09. Indicated that staff could not obtain a reading of 0.01-0.09 if using the testing strips supplied by this facility for use, this is not possible. Denies any other testing strips available in the facility to account for the observed values documented. Confirmed that manual readings found on documentation provided by facility show chlorine levels that cannot be duplicated with the testing strips supplied. Employee A confirmed that CM130 had stopped being used to check chlorine levels as of 12/16/2021 due to unable to get PM (preventive maintenance) kits, currently on back-order due to COVID-19 pandemic.	V 196		
V 250	DIALYS PROPORT-MONITOR PH/CONDUCTIVITY CFR(s): 494.40(a)	V 250		3/1/22

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FORT WAYNE SOUTH DIALYSIS	302 E PETTIT AVE FORT WAYNE, IN 46806

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 250	Continued From page 12 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 observation, record review, and interview, the facility failed to ensure the solution used to test for pH and conductivity was not expired in 1 of 1 facility. Findings Include: 1. A policy titled "Phoenix Meter Disinfection and Calibration Verification" dated October 2020 was provided by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to, "Follow manufacturer's labeling for the solution for expiration dates." 2. An observation on 1/25/2022 at 11:07 a.m. of 2 bottles of Mesa Labs Conductivity Standard Solution 50 ms/cm located at the nurse's station on the treatment floor was found to have been expired as of 11/8/2021. One bottle was noted to be 1/2 empty and the second bottle was unopened. 3. An interview with the biomed technician was completed on 1/25/2022 at 11:07 a.m. The biomed technician was shown the expired bottles of conductivity solution that had expired on 11/8/2021 per manufacturer's recommendation.	V 250		

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V 250	Continued From page 13 Agreed the solution should not be used and needed discarded immediately. The biomed technician was observed discarding the expired solutions and replacing with solution that was not expired.	V 250		
V 401	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 observation, record review, and interview, the facility failed to ensure the building was free from defects and hazards that would prevent the risk of falls and injury for staff and patients in 1 of 1 facility. Findings Include: 1. A policy titled "Infection Control for Dialysis Facilities" dated October 2021 was provided by Employee A 1/26/2022 at 9:00 a.m. The policy indicated, but was not limited to, "After each treatment the floor area around chair/bed and dialysis delivery system will be evaluated and cleaned if necessary." 2. During an observation on 1/25/2022 at 11:29 a.m. two large puddles of water were observed in front of station 14. During the observation period of 10:25 a.m. to 12:15 a.m. this water remained on the floor in a high traffic area where both staff and patients were using.	V 401		3/1/22

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V 401	Continued From page 14 3. An interview was completed with Employee A on 1/25/2022 at 1:33 p.m. Employee A agreed that water on the treatment floor was a hazard and should be cleaned up immediately to prevent a slip or fall.	V 401		
V 402	PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY CFR(s): 494.60(a) The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure the building was maintained to ensure the safety of patients and staff in 1 of 1 facility. Findings Include: 1. During an observation on 1/25/2022 at 11:00 a.m. located at the nurse's station was a cabinet used to store clean supplies. The shelf inside the cabinet was broken and the clean supplies (syringes) were being stored in the cabinet on top of the broken shelf. 2. During an observation on 1/25/2022 at 12:14 p.m. a cabinet door was found ajar containing supplies to make bleach water at the technician station. The door had several old strips of paper tape in place appearing to be used to keep the cabinet door shut. Attempted to shut cabinet door several times, however, door immediately would	V 402		3/1/22

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V 402	Continued From page 15 swing back open. A slide out drawer was observed with normal saline bags. This drawer was full and extremely heavy. When attempting to open the drawer, using a lot of force to open, noted drawer had fallen off rail and appeared broken. 3. An interview was completed with Employee I on 1/25/2022 at 12:25 p.m. Employee I acknowledged the broken cabinet door and drawer at the technician's station. Indicated the tape on the outside of the cabinet was an attempt to keep the cabinet door closed but has been unsuccessful. Advised to watch opening the saline drawer due to it being broken. Indicated heavy drawer with saline would land on my foot. 4. An interview was completed with Employee A on 1/25/2022 at 1:33 p.m. Employee A was advised of the broken cabinet drawers and doors located at the nurses and technicians' stations and indicated these issues needed attention. No further information was provided.	V 402		
V 403	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 observation and interview, the facility failed to maintain dialysis chairs in a safe and	V 403		3/1/22

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V 403	Continued From page 16	V 403		

functional working condition in 1 of 1 facility.

Findings Include:

1. During an observation on 1/26/2022 at 11:11 a.m. a dialysis chair at station 6 had a tear in the vinyl fabric located in the middle of the seat that appeared to be 4-6 inches long. The right arm vinyl covering was also torn. A chair located at station 16 had a 4-6-inch tear located in the middle of the seat. Beneath the torn vinyl fabric, linen appearing fabric was observed.

2. During an observation on 1/28/2022 at 8:30 a.m. upon arriving at the dialysis station observed 4 dialysis treatment chairs sitting outside near the dumpster.

3. An interview was completed with Employee A on 1/25/2022 at 1:33 p.m. Employee A indicated that the previous week there was a walk through with Employee M. Employee M identified repairs needed within the facility and was aiding facility with plan for needed repairs and maintenance issues. Advised that facility received 5 new dialysis chairs last year with plan to receive 5 more this year. Agreed that torn vinyl on the dialysis chairs made it impossible to effectively clean the chairs to ensure the safety of the patients and staff.

4. During an interview with Employee A and Employee B on 1/26/2022 at 2:15 p.m. identified torn chairs found in use on the treatment floor was described. Employee A agreed that cleaning and disinfecting chairs in this state of disrepair is difficult. Could not explain how the fabric beneath the torn vinyl is cleaned of any hazardous fluids.

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V 455	Continued From page 17	V 455		
V 455	PR-PRIVACY & CONFIDENTIALITY-RECORDS CFR(s): 494.70(a)(4) The patient has the right to- (4) Privacy and confidentiality in personal medical records; This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the facility failed to maintain the privacy and confidentiality of patient information during 2 of 3 observations. Findings Include: 1. A policy titled "Patient's Rights" dated October 2021 was provided by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to "27. To know my medical records and the information contained will be considered private and confidential and only be released in compliance with state and federal law." 2. An observation on 1/25/2022 at 11:23 a.m. evidenced the Patient Entrance Evaluation Tracker for COVID-19 displaying confidential patient information near the entrance/exit of dialysis treatment floor. The documentation contained patient names, and a series of COVID-19 questions used to identify COVID-19 illness. The information was located on the wall at eye level. 3. An observation on 1/28/2022 at 10:40 a.m. evidenced the Patient Entrance Evaluation Tracker for COVID-19 displaying confidential patient information near the entrance/exit of the	V 455		3/1/22

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V 455	Continued From page 18 dialysis treatment floor. Located in the same place as observed on 1/26/2022. 4. An interview with Employee A was completed on 1/25/2022 at 1:33 p.m. Employee A was notified of private/confidential patient information being displayed near the entrance/exit of the dialysis treatment floor. A door used by staff, patients, and visitors. The Patient Entrance Evaluation Tracker for COVID-19 is located on the wall at eye level and is displaying private/confidential patient information. No further information was provided. 5. An interview with Employee B was completed on 1/28/2022 at 11:45 a.m. Employee B was notified of confidential patient information still be displayed at eye level upon entering/exiting the treatment floor. Advised information displayed is the Patient Entrance Evaluation Tracker for COVID-19 used for patients and visitors. Employee B indicated that she had placed a blank sheet of paper over the information on day 1 of survey. Advised her that the pages were fanned out when placed in container displaying patient information.	V 455		
V 503	PA-APPROPRIATENESS OF DIALYSIS RX CFR(s): 494.80(a)(2) The patient's comprehensive assessment must include, but is not limited to, the following: (2) Evaluation of the appropriateness of the dialysis prescription, This STANDARD is not met as evidenced by:	V 503		3/1/22

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Based on record review and interview, the facility failed to ensure patient's TW (target weight) were met post treatment in 6 of 10 records reviewed. (Patient 3, 4, 5, 8, 9, and 10)

Findings Include:

1. A policy titled "Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment" dated April 2021 was provided by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to, "Post Treatment Data Collection Assessment:" ... "16. If abnormal finding (s) or concern is identified post treatment, this needs to be reported to the licensed nurse. The licensed nurse will assess the patient prior to discharge." ... "Abnormal Findings" ... "Fluid Status" ... "Post Treatment" ... "If patient is above or below 1 kg (kilogram) from the target weight."

2. The medical record for Patient 3 was reviewed on 1/25/2022 and evidenced the following with no documentation of nurse being notified of Target Weight not met within 1 kg:
1/10/2022 Target weight=127 kg Post-weight 132.0
1/19/2022 Target weight=127 kg Post-weight 124.6
1/21/2022 Target weight=127 kg Post-weight 116.3

3. The medical record for Patient 4 was reviewed on 1/25/2022 and evidenced the following with no documentation of nurse being notified of Target Weight not met within 1 kg:
1/15/2022 Target weight=97.5 kg Post-weight 98.9
1/18/2022 Target weight=97.5 kg Post-weight

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V 503	Continued From page 20	V 503		

99.9

4. The medical record for Patient 5 was reviewed on 1/25/2022 and evidenced the following with no documentation of nurse being notified of Target Weight not met within 1 kg:
1/12/2022 Target weight=92.5 kg Post-weight 93.6
1/19/2022 Target weight=92.5 kg Post-weight 87.5
1/21/2022 Target weight=92.5 kg Post-weight 87.9
1/24/2022 Target weight=90 kg Post-weight 88.2

5. The medical record for Patient 8 was reviewed on 1/26/2022 and evidenced the following with no documentation of nurse being notified of Target Weight not met within 1 kg:
1/11/2022 Target weight=97.5 kg Post-weight 99.8
1/13/2022 Target weight=97.5 kg Post-weight 99.8
1/15/2022 Target weight=97.5 kg Post-weight 99.3
1/20/2022 Target weight=97.5 kg Post-weight 99.0
1/25/2022 Target weight=97.5 kg Post-weight 99.8

6. The medical record for Patient 9 was reviewed on 1/26/2022 and evidenced the following with no documentation of nurse being notified of Target Weight not met within 1 kg:
1/19/2022 Target weight=48 kg Post-weight 49.1

7. The medical record for Patient 10 was reviewed on 1/26/2022 and evidenced the following with no documentation of nurse being notified of Target Weight not met within 1 kg:

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V 503	Continued From page 21 1/10/2022 Target weight=79 kg Post-weight 81 1/13/2022 Target weight=79 kg Post-weight 80.9 1/17/2022 Target weight=79 kg Post-weight 80.3 8. During an interview with Employee A and Employee B on 1/27/2022 at 10:37 a.m. both staff members were notified of post target weight not being met with no documentation found the licensed nurse was notified. Both Employee A and Employee B acknowledge findings and reported that PCT's (patient care technicians) do not have access to free chart, can only pick from pre-set phrases. This is an update they are expecting to the electronic medical record system. No further information was provided.	V 503		
V 506	PA-IMMUNIZATION/MEDICATION HISTORY CFR(s): 494.80(a)(3) The patient's comprehensive assessment must include, but is not limited to, the following: Immunization history, and medication history. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to ensure that a TB (tuberculosis) status was known and documented prior to admission to the facility in 1 of 1 new admissions records reviewed. (Patient 1) Findings Include: 1. A policy titled "Tuberculosis Infection Control Policy" dated April 2018 was provided by Employee A on 1/26/2022 at 12:55 a.m. The policy indicated but was not limited to, "2. Patients	V 506		3/1/22

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with chronic kidney disease (CKD) are considered high risk for progression from latent TB infection (LTBI) to active TB disease and will be screened for TB prior to first treatment" ... "5. A Chest X-ray (CXR) obtained for the purposes that has been interpreted by a radiologist as clear, negative, normal, or unremarkable, is acceptable" ... "Permanent Admission New to Dialysis OR Permanent Admission from a Non-DaVita Facility is to provide the following documentation prior to first treatment, unless otherwise required by applicable state law: Requirement 1: Negative TST (one step) completed within three (3) months prior to admission: OR Requirement 2: Negative TST (two-step) completed within three (3) months prior to first treatment: OR Requirement 3: Negative QFT-G or T-SPOT completed within three (3) months prior to first treatment; OR Requirement 4: CXR and documented medical follow-up that was completed after a positive test (TST, QFT-G, or T-SPOT) IF the patient was found positive on the TST, QFT-G, or T-SPOT completed as the preadmission test within three (3) months prior to the first treatment; OR Requirement 5: CXR that was completed within three (3) months prior to first treatment for the patient who has a history of a past positive TST or positive QFT-G or T-SPOT and can provide documentation of the medical follow-up to the positive test (e.g. patient had completed treatment for latent TB infection); OR Requirement 6: CXR completed within three (3) months prior to first treatment IF unable to obtain documented results of a negative TST< QFT-G, or T-SPOT prior to first treatment, per requirements #1, #2, or #3."

2. A record review was completed on Patient 1 on

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V 506	Continued From page 23 1/25/2022, admission date 12/28/2021. The facility was unable to provide the medical documentation of a negative PPD skin test result completed prior to admission or a chest x-ray report by a radiologist indicating: clear, negative, normal, or unremarkable result. 3. An interview was completed with Employee A on 1/26/2022 at 9:33 a.m. Employee A confirmed that Patient 1 was admitted to the facility on 12/28/2021 as indicated on the Kardex (handwritten by Employee A). Confirmed that there was no PPD test completed the day of admission or prior to admission to the facility. Unable to provide a copy of a chest x-ray report prior to admission indicating a result of clear, negative, normal, or unremarkable.	V 506		
V 543	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 record review and interview, the facility failed to report abnormal BP's (blood pressures) to the licensed nurse per policy and procedure in 5 of 10 records reviewed. (Patient 2, 5, 7, 8, and 9) Findings Include: 1. A policy titled "Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment" dated April 2021 was provided by Employee A on	V 543		3/1/22

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1/26/2022 at 9:00 a.m. The policy indicated but was not limited to, "Abnormal findings outside any patient specific physician ordered parameters will be reported to the licensed nurse immediately (refer to "Abnormal Findings" section of this policy)." ... "Blood pressure: Pre-dialysis: Systolic greater than 180 mm/Hg or less than 90 mm/Hg Diastolic greater than or equal to 100 mm/Hg" ... "Blood Pressure-Intradialytic: Difference of 20 mm/Hg increase or decrease from patient's last intradialytic treatment BP reading." ... "Blood Pressure Post Treatment: Standing systolic BP greater then 140 mm/Hg or less than 90 mm/Hg. Standing diastolic BP greater than 90 mm/Hg or less than 50 mm/Hg." ... "Sitting systolic BP greater than 140 mm/Hg or less than 90 mm/Hg. Sitting diastolic BP greater than 90 mm/Hg or less than 50 mm/Hg."

2. The medical record/treatment sheets for Patient 2 were reviewed on 1/25/2022 and evidenced the following:

A physician order entered on Patient 2's Kardex dated 7/29/2013-Notify RN (registered nurse) for systolic pressure <100 or >200.

Treatment sheet dated 1/12/2022 Intradialytic BP's: 94/44 at 3:01 p.m., and 69/29 at 4:17 p.m., not reported to RN.
Treatment sheet dated 1/14/2022 Pre standing BP 87/52, Intradialytic BP's: 10:46 a.m. 90/55, and 82/50 at 11:01 a.m., not reported to RN.
Treatment sheet dated 1/19/2022 Intradialytic BP's: 243/135 at 2:32 p.m., 234/161 at 3:01 p.m., and 80/62 at 3:32 p.m., not reported to RN.
Treatment sheet dated 1/21/2022 Post standing BP 99/32, Intradialytic BP's: 99/50 at 1:32 p.m., 94/45 at 3:32 p.m. and 98/53 at 4:31 p.m., not

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reported to RN.
Treatment sheet dated 1/24/2022 Post sitting BP 94/27, Intradialytic BP's: 91/53 at 12:32 p.m. and 94/27 at 4:02 p.m., not reported to RN

3. The medical record/treatment sheets for Patient 5 were reviewed on 1/25/2022 and evidenced the following:

A physician order entered on Patient 5's Kardex dated 2/17/2016-Notify RN (registered nurse) for systolic pressure <100 or >200.

The treatment sheet dated 1/10/2022 Post sitting BP 210/79, Intradialytic BP's 205/92 at 11:02 a.m., 205/85 at 11:32 a.m., 204/98 at 12:33 p.m., and 203/94 at 1:02 p.m., not reported to RN.
The treatment sheet dated 1/12/2022 Intradialytic BP's 207/81 at 11:33 p.m., 221/90 at 12:02 p.m., 231/101 at 12:32 p.m. and 224/96 at 1:02 p.m., not reported to the RN.
The treatment sheet dated 1/14/2022 Intradialytic BP's 208/67 at 11:02 a.m. and 202/86 at 12:12 p.m., not reported to the RN.
The treatment sheet dated 1/19/2022 Post BP 211/88, Intradialytic BP's 211/64 at 11:32 a.m., 203/77 at 12:32 p.m., 203/69 at 1:02 p.m., 220/78 at 1:32 p.m., and 252/89 at 1:36 p.m., not reported to RN.
The treatment sheet dated 1/24/2022 Intradialytic BP's 210/87 at 11:32 a.m., 235/92 at 12:32 p.m., 223/91 at 1:03 p.m., 210/68 at 1:16 p.m., and 242/101 at 1:33 p.m., not reported to RN.

4. The medical record/treatment sheets for Patient 7 were reviewed on 1/26/2022 and evidenced the following:

A physician order entered on Patient 7's Kardex

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dated 2/1/2013-Notify RN (registered nurse) for systolic pressure <100 or >200.

The treatment sheet dated 1/14/2022 Post Sitting BP 219/96, Intradialytic BP 203/93 at 6:02 p.m., not reported to RN.
The treatment sheet dated 1/17/2022 Post sitting BP 205/102, Intradialytic BP's 22/90 at 3:02 p.m., 214/108 at 5:02 p.m., 223/110 at 6:02 p.m. and 205/102 at 6:14 p.m., not reported to RN.

5. The medical record/treatment sheets for Patient 8 were reviewed on 1/26/2022 and evidenced the following:

A physician order entered on Patient 8's Kardex dated 2/25/2013-Notify RN (registered nurse) for systolic pressure <100 or >200.

The treatment sheet dated 1/11/2022 Intradialytic BP's 87/34 at 7:01 a.m., 83/35 at 7:31 a.m., and 97/40 a.m., not reported to RN.
The treatment sheet dated 1/13/2022 Intradialytic BP 98/62 at 8:01 a.m., not reported to RN.
The treatment sheet dated 1/25/2022 Intradialytic BP's 95/49 at 9:02 a.m., 95/45 at 10:35 a.m., and 80/52 at 10:47 a.m., not reported to RN.

6. The medical record/treatment sheets for Patient 9 were reviewed on 1/26/2022 and evidenced the following:

A physician order entered on Patient 9's Kardex dated 1/6/2021-Notify RN (registered nurse) for systolic pressure <100 or >200.

The treatment sheet dated 1/10/2022 Post sitting BP 230/116, Intradialytic BP's 218/102 at 4:31 p.m., 222/112 at 5:01 p.m., and 242/116 at 5:25

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V 543	Continued From page 27 p.m., not reported to RN. The treatment sheet dated 1/12/2022 Post sitting BP 208/87, Intradialytic BP's 208/87 at 4:51 p.m. not reported to RN. 7. An interview with Employee A and Employee B was completed on 1/27/2022 at 10:37 a.m. Both Employees were present when notified of out-of-range blood pressures not reported to the RN or documented within the electronic medical record. No further information was provided.	V 543		
V 544	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 observation, record review, and interview, the facility failed to ensure BFR (blood flow rates) and DFR (dialysate flow rates) were followed per physician order in 10 of 10 records reviewed. (Patient 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10) Findings Include: 1. A policy titled "Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment" dated April 2021 was provided by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to, "Patient identity, prescription and machine settings are verified by teammate prior to initiation of treatment with the exception of blood flow rate which is verified and documented	V 544		3/1/22

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when the ordered rate is obtained after onset of treatment. The prescription components are confirmed by a licensed nurse within one (1) hour of treatment initiation along with the nursing assessment or as allowable by state law. Prescription components include but are not necessarily limited to:" ... "f. Blood flow rate" ... "g. Dialysate flow rate." ... "10. If the prescription is not being met (including dialysis flow rate or change to/inability to obtain prescribed blood flow rate) the reason will be documented and the licensed nurse informed."

2. Record review for Patient 1 was completed on 1/25/2022 and evidenced the following incorrect BFR's with no documentation for change in physicians prescribed orders:
1/8/2022 Ordered BFR=350 Patient 1 ran a BFR of 195 partial treatment.
1/20/2022 Ordered BFR=350 Patient 1 ran a BFR of 345 partial treatment.

3. Record review for Patient 2 was completed on 1/25/2022 and evidenced the following incorrect BFR's and DFR's with no documentation for change in physicians prescribed orders:
1/10/2022 Ordered BFR=350 Patient 2 ran a BFR of 300 during treatment.
1/12/2022 Ordered BFR=350 Patient 2 ran a BFR of 325 last ½ hour of treatment.
1/14/2022 Ordered BFR=350 Patient 2 ran a BFR of 200-300 during treatment.
1/17/2022 Ordered BFR=350 Patient 2 ran a BFR of 300 during treatment.
1/19/2022 Ordered BFR=350 Patient 2 ran a BFR of 300 during treatment.
1/21/2022 Ordered BFR=350, DFR= 500 Patient 2 ran a BFR of 345 and DFR of 600 during treatment.

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V 544	Continued From page 29 1/24/2022 Ordered BFR=350 Patient 2 ran a BFR of 325 during treatment. 4. Record review for Patient 3 was completed on 1/25/2022 and evidenced the following incorrect BFR's with no documentation for change in physicians prescribed orders: 1/10/2022 Ordered BFR=400 Patient 3 ran a BFR of 350 during treatment. 1/19/2022 Ordered BFR=400, Ordered DFR=500 Patient 3 ran a BFR of 350 and a DFR of 600 during treatment. 1/21/2022 Ordered BFR=400, Ordered DFR=500 Patient 3 ran a BFR of 350 and DFR of 600 during treatment. 1/24/2022 Ordered BFR=400 Patient 3 ran a BFR of 350 during treatment. 5. Record review for Patient 4 was completed on 1/25/2022 and evidenced the following incorrect BFR's and DFR's with no documentation for change in physicians prescribed orders: 1/15/2022 Ordered BFR=450 Patient 4 ran a BFR of 400 during treatment. 1/18/2022 Ordered BFR=450 Patient 4 ran a BFR of 390 during treatment. 1/20/2022 Ordered DFR=500 Patient 4 ran a DFR of 600 during treatment. 6. Record review for Patient 5 was completed on 1/25/2022 and evidenced the following incorrect BFR's and DFR's with no documentation for change in physicians prescribed orders: 1/10/2022 Ordered BFR=400 Patient 5 ran a BFR of 350 during treatment. 1/12/2022 Ordered BFR=400 Patient 5 ran a BFR of 350 during treatment. 1/14/2022 Ordered BFR=400 Patient 5 ran a BFR of 350 during treatment.	V 544		

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V 544	Continued From page 30 1/17/2022 Ordered BFR=400 Patient 5 ran a BFR of 350 during treatment. 1/18/2022 Ordered BFR=400 Patient 5 ran a BFR of 300 during treatment. 1/21/2022 Ordered DFR=500 Patient 5 ran a DFR of 600 during treatment. 7. Record review for Patient 6 was completed on 1/26/2022 and evidenced the following incorrect BFR's with no documentation for change in physicians prescribed orders: 1/22/2022 Ordered BFR=450 Patient 6 ran a BFR of 300-440 during treatment. 8. Record review for Patient 7 was completed on 1/26/2022 and evidenced the following incorrect BFR's and DFR's with no documentation for change in physicians prescribed orders: 1/17/2022 Ordered BFR=350 Patient 7 ran a BFR of 355 partial treatment. 1/19/2022 Ordered DFR=600 Patient 7 ran a DFR of 500 during treatment. 1/21/2022 Ordered DFR=600 Patient 7 ran a DFR of 500 during treatment. 1/24/2022 Ordered BFR=350 Patient 7 ran a BFR of 250 partial treatment. 9. Record review for Patient 8 was completed on 1/26/2022 and evidenced the following incorrect BFR's with no documentation for change in physicians prescribed orders: 1/8/2022 Ordered BFR=450 Patient 8 ran a BFR of 420 partial treatment. 1/13/2022 Ordered BFR=450 Patient 8 ran a BFR of 280 partial treatment. 1/15/2022 Ordered BFR=450 Patient 8 ran a BFR of 325-400 partial treatment. 1/20/2022 Ordered BFR=450 Patient 8 ran a BFR of 400 partial treatment.	V 544		

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10. Record review for Patient 9 was completed on 1/26/2022 and evidenced the following incorrect BFR's with no documentation for change in physicians prescribed orders:
1/12/2022 Ordered BFR=350 Patient 9 ran a BFR of 300 partial treatment.
1/19/2022 Ordered BFR=350 Patient 9 ran a BFR of 300 partial treatment.
1/22/2022 Ordered BFR=350 Patient 9 ran a BFR of 325 partial treatment.

11. Record review for Patient 10 was completed on 1/26/2022 and evidenced the following incorrect BFR's and DFR's with no documentation for change in physicians prescribed orders:
1/10/2022 Ordered BFR=350 Patient 10 ran a BFR of 400 during treatment.
1/13/2022 Ordered BFR=350 Patient 10 ran a BFR of 450 during treatment.
1/19/2022 Ordered DFR=600 Patient 10 ran a DFR of 500 during treatment.
1/21/2022 Ordered DFR=500 Patient 10 ran a DFR of 600 during treatment.

12. During an interview with Employee A and Employee B on 1/27/2022 at 10:37 a.m. both staff members were notified of significant findings with each medical record review evidencing blood flow and dialysate flow rates not being followed per physician order. Employee B acknowledged findings and agreed that staff need to document why prescription is not being met. Notified due to dialysate shortage all patients are to run a DFR of 500. Adopted by governing body on 1/19/2022. Agreed that physician orders followed by staff to set parameters on the dialysis machine on this date were not updated in the Kardex as the new physician order.

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V 675	CFC-LABORATORY SERVICES CFR(s): 494.130	V 675		3/1/22

This CONDITION is not met as evidenced by:
An Immediate Jeopardy related to §494.130 Laboratory Services was identified and announced on 1/28/2022 at 9:00 a.m. The facility's immediate jeopardy removal of immediacy plan and actions were determined to have removed the immediacy component of the immediate jeopardy on 1/28/2022, at 2:00 p.m.

The immediate jeopardy began January 1, 2021, when the facility Laboratory Refrigeration Temperature logs were found to be incomplete and/or missing laboratory refrigerator temperature monitoring. The facility failed to follow their own policy titled "Laboratory Specimens Requiring Refrigeration" provided by Employee A. The facility failed to monitor and document the laboratory refrigerator temperature twice daily during operating hours of the facility beginning January 1, 2021, through January 25, 2022. Lab temperature documentation logs were missing for the months of March 2021, June 2021, July 2021, August 2021, September 2021, October 2021, and November 2021. Partial and/or incomplete monitoring of laboratory refrigerator log was found in January 2021, April 2021, May 2021, December 2021, and January 2022. On 1/25/2022 at 10:55 a.m. the laboratory refrigerator temperature was noted at 17 degrees Fahrenheit. Lab specimens were observed in the refrigerator. The subsequent failures could have resulted in serious harm, serious injury, or death involving all current and future dialysis patients admitted to this facility.

The cumulative effect of this systemic problem

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resulted in the facility being out of compliance with §494.130: Laboratory Services.

Based on observation, record review, and interview, the facility failed to follow their own policy to prevent the potential for serious harm, serious injury, or death for all current patients and all future patients admitted to this facility related to laboratory storage, monitoring, and documentation of the laboratory refrigerator temperature log.

Findings include:

1. A policy titled "Laboratory Specimens Requiring Refrigeration" dated March 2016 was provided by the facility administrator on 1/27/2022 at 9:17 a.m. The policy indicated but was not limited to, "1. Laboratory specimens that require refrigeration are stored in the facility refrigerator designated for "Laboratory Specimens" only. 2. The laboratory refrigerator is checked daily during normal operating hours for cleanliness and to verify the temperature remains between 36 F and 46 F. The laboratory temperature is to be checked by a licensed nurse or designee daily. 3. The temperature will be documented on the Laboratory Refrigerator Temperature Log. 4. A separate temperature log is maintained for each laboratory refrigerator present in the facility (if applicable). Refrigerators that do not maintain temperatures in the acceptable, stated range will be repaired or replaced as soon as possible. Facility teammate must notify their Biomed technician."

2. A document titled "Medication Refrigerator Temperature Log" dated December 2021 was provided by Employee A on 1/27/2022 at 8:41

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a.m. The summarized document showed the laboratory temperature documentation log for the month of December 2021. Missing PM check on December 11, 2021, and missing staff initials on PM check on December 13, 2021.

3. Documents titled "Medication Refrigerator Temperature Log" dated January 2021, February 2021, April 2021, and May 2021 were provided by Employee B on 1/27/2022 at 10:16 a.m. The summarized documents showed the laboratory temperature documentation log for the above listed months in 2021. January 2021-missing documentation from January 1-22 of 2021. February 2021-documentation complete for entire month. One temperature reading noted at 22 F-action taken by staff member to resolve. April 2021-Missing documentation noted on February 10th, 11th, 14th, 15th, 22nd, 23rd, 24th, 25th. One out-of-range temperature of 50 F with staff action of "decreased temp" documented. May 2021-Missing documentation noted on May 1st, 7th, 8th, 13th, 15th, 17th, 20th, 22nd, 25th, 26th, 29th. Staff unable to provide documentation of laboratory temperature monitoring for the months of March, June, July, August, September, October, and November of 2021.

4. The following protocols for dialysis were based on laboratory results:

A document titled "Liquacel Oral Nutrition Supplement (ONS) Protocol (Rev. 2.0) revised on 2/2017 was provided by Employee B. The summarized document indicated but was not limited to, the management of ESRD (End Stage Renal Disease) patient's Serum Albumin status to assist with the administration and need of an oral nutritional supplement. This protocol is based on

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laboratory results.

A document titled "Iron Works (rev 3.5)" revised on 12/6/2012 was provided by Employee B on 1/27/2022 at 10:16 a.m. The summarized document indicated but was not limited to, targeting Ferritin and TSAT serum in the blood and dosing and administering IV (intravenous) Iron medication per protocol.

A documented titled "Shape Personalized Dosing, Epoetin Alfa IV MDV DOSIS Protocol (ver. 10.0) for ICHD Patients" dated 8/7/2019 was provided by Employee B on 1/27/2022 at 10:16 a.m. The summarized document indicated but was not limited to, targeting serum Hemoglobin ranges of 10-11 g/dL, and administering an ESA (erythropoiesis stimulating agent) to maintain patients hemoglobin level within that range and to reduce the need for blood transfusions. Dosage of medication based on laboratory results.

A document titled "DaVita Mineral and Bone Disorder Management IV Vitamin D Treatment Tool" dated March 2011 was provided by Employee B on 1/27/2022 at 10:16 a.m. The summarized document indicated but was not limited to, a tool used by staff to for the management of IV vitamin D sterols, phosphate binders and calcimimetic agents (medications used to treat conditions in ESRD patients) in the treatment of renal osteodystrophy in ESRD patients based on laboratory results.

A document titled "Parsabiv (AMG 416 Etelcalcetide) Dose Adjustment/Monitoring Protocol Ca > 9.5 (rev. 2.0)" dated October 2017 was provided by Employee B on 1/27/2022 at 10:16 a.m. The summarized document indicated

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but was not limited to the dosing of Parsabiv (medication used to treat Intact PTH, calcium, and phosphorus levels in the blood) based on the following laboratory levels: Intact PTH, Calcium, Phosphorus.

A document titled "Parsabiv (AMG 416 Etelcalcetide) Dose Adjustment/Monitoring Protocol Ca >10.0 (rev. 2.1)" dated October 2017 was provided by Employee B on 1/27/2022 at 10:16 a.m. The summarized document indicated but was not limited to the dosing of Parsabiv (medication to treat Intact PTH, calcium and phosphorus levels in the blood) based on the following laboratory levels: Intact PTH, Calcium, Phosphorus.

A document titled "HD Cinacalcet Daily Dosing Adjustment/Monitoring Protocol. Ca > 10.o (rev. 1.0)" dated May 2016 was provided by Employee B on 1/27/2022 at 10:16 a.m. The summarized document indicated but was not limited to the dosing of Cinacalcet (medication used to treat calcium levels in the blood) based on the following laboratory levels: Intact PTH levels, Calcium levels, and phosphorus levels.

5. A document titled "Hemodialysis Admission Lab Orders" version 1.7 was provided by Employee B on 1/27/2022 at 10:16 a.m. The summarized document indicated but was not limited to the laboratory drawing schedule for each patient in the dialysis facility. Monthly labs include: Composite without calcium and phosphorus, an iron panel, calcium and phosphorus, kinetic panel, creatinine, glucose (if diabetic), sodium, ferritin, Hepatitis B antigen, and PTH. Biweekly: hemoglobin & Hematocrit. Quarterly: (if diabetic) Hemoglobin A1C and

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Aluminum. Hepatitis B surface Antibody, quantitative. Upon admission: Hepatitis Antibody Core. PRN (as needed): magnesium & potassium.

6. During an observation on 1/25/2022 at 10:55 a.m. the laboratory refrigerator was noted to have a temperature of 17 degrees F (Fahrenheit).

7. During an observation on 1/27/2022 at 11:00 a.m. the laboratory refrigerator was noted to have a temperature of 49 degrees F and was full of laboratory specimens.

8. During an interview with the Employee A and Employee B on 1/25/2022 at 1:23 p.m., both were unaware of the out-of-range temperature and were unable to advise of recommended temperature range. Agreed to check policy before giving a response.

9. An interview with Employee D was completed on 1/25/2022 at 4:05 p.m. Employee D indicated the recommended laboratory temperature should be between 38-48 F but was unsure. Would provide policy to clarify exact temperature requirements. Employee D indicated the thermometer in the lab refrigerator was broken.

10. An interview with Employee A was completed on 1/26/2022 at 2:04 p.m. Employee A indicated unsure of when the lab temperature was last monitored and documented.

11. An interview with Employee E was completed on 1/27/2022 at 8:43 a.m. Employee E indicated that the opening nurse or PCT (patient care technician) was responsible for checking the laboratory temperatures daily. Indicated all labs,

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except stat labs, were sent to DaVita Labs in Florida to be resulted. Indicated that the lab temperature is to be monitored and documented on the Medication Refrigerator Temperature log daily and when out of range to immediately notify the facility administrator. Indicated this is not documented in the electronic medical record, only on paper log. Did not know what algorithms/protocols were used to dose medications based on lab results. If lab specimen was stored in a refrigerator that is out of temperature range Employee E indicated that lab results would be inaccurate. Indicated lab temperatures have not been monitored and documented since January 1, 2022. Unable to voice what labs were drawn on each patient and how often or the process of packing and shipping labs, and pick-up schedules. Did indicate labs were picked up daily Monday-Friday, unsure of times. Indicated there is a process and staff have a cheat sheet with the specific process to follow.

12. An interview with Employee B was completed on 1/27/2022 at 8:56 a.m. Employee B indicated the opening nurse or PCT was responsible for monitoring and documenting the laboratory refrigerator temperatures twice daily at open and close. All laboratory tests were sent to DaVita Labs for resulting in Florida. Monitoring of labs is completed twice a day and recorded on the Medication Refrigerator Temperature log, a paper log. Algorithms/protocols used to dose medications within the facility include, iron, hemoglobin, dialysis adequacy (Kt/v), Mineral Bone Metabolism (phosphorus, calcium, parathyroid hormone). All potassium values are called and reported to the physician or nurse practitioner. Lab alerts (out of range labs) are faxed to the facility with the out-of-range labs. If

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critical labs are resulted, the critical labs are called to the facility. If lab specimens are stored in a refrigerator that is out of range what can happen to the lab results, indicated hemolysis. Indicated that lab temperature monitoring and documentation has not been completed since January 1, 2022. Indicated labs were picked up Monday-Friday via Fed Ex between 4:00 p.m. and 6:00 p.m. and stored in refrigerator until then. If labs were drawn on Saturdays, staff must call Fed Ex for pickup.

13. An interview was completed with Employee A on 1/27/2022 at 9:17 a.m. Employee A indicated that the opening nurse or PCT is responsible for monitoring and documenting the laboratory refrigerator temperature twice daily, at open and close. All labs, except STAT labs are sent to DaVita Labs in Florida to be resulted. Lab temperatures are to be documented on the Medication Temperature log, not entered into an electronic medical record. All out of range lab temperatures are to be reported to the facility administrator and biomed technician. Out of range labs are reported to the physician. DaVita Labs sends out-of-range lab results via fax for each patient and call the facility with critical labs. If lab tubes are stored in out-of-range temperatures this could result in hemolysis and inaccurate lab results. Stated there are "temperature parameters for a reason." The last time the lab refrigerator was monitored and documented was December 20, 2021, and for the past year the months of June 2021 and November 2021 no documentation was found. Lab specimens are shipped Monday through Friday via Fed Ex between the hours of 4-6 p.m. Stated temperature yesterday, 1/26/2022, prior to leaving the facility was 42 degrees F. On

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1/27/2022, upon arrival to facility the temperature was 50 degrees F.

14. An interview was completed with Employee F on 1/27/2022 at 9:50 a.m. Employee F indicated that the lab refrigerator temperature was to be monitored and documented twice daily at 5:00 a.m. and again at 5:00 p.m. The opening nurse was to complete this task. All labs are sent to DaVita Labs in Florida to be resulted. Algorithms and protocols are used based on lab results to dose medications to address anemia (low blood counts), iron, phosphorus, calcium parathyroid levels. Specimens stored in out-of-range temperature can result in a ruined specimen and inaccurate lab results. Employee F indicated that she opens the clinic 3-4 day a week but cannot recall a time the laboratory refrigerator was not monitored or documented by self however, indicated it has not been monitored and documented per policy. Reports multiple labs being drawn for patients on varying schedules, including CBC (complete blood counts), chemistry panels, vitamin D levels, A1C levels (used to summarize patient blood glucose levels) as well as others she cannot recall at this time. Indicated that Patient 11 was admitted to hospital for anemia the first of January of 2022 but unsure if related to abnormal lab result.

15. An interview was completed with Employee G on 1/27/2022 at 10:05 a.m. Employee G indicated that the laboratory temperature was completed by the PCT assigned the labs for the day but was unsure and would find out. The lab temperature is to be completed each night. All lab specimens are sent to DaVita Labs in Florida Monday through Friday. Did not know where the temperatures were to be recorded. Unsure of which algorithms

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V 675	Continued From page 41 or protocols are used to dose medications based on lab results. Indicated that lab specimens stored in out-of-range temperatures could result in incorrect values and cause harm to patients. Indicated that lab temperatures had not been monitored or documented in the past 60 days. 16. An interview was completed with Employee B on 1/27/2022 at 11:00 a.m. The lab temperature checked read 49 F. Refrigerator noted to be full of lab specimens. Employee B was notified of finding and indicated the temperature was not in recommended range. Employee B instructed staff to discard all lab specimens in the refrigerator and to stop drawing labs until temperature issue is resolved. Indicated the out of range specimens located in refrigerator if sent to the lab, could result in inaccurate lab results. 17. An interview was completed with the Medical Director on 1/27/2022 at 1:20 p.m. The medical director indicated that she had been made aware by staff of the incomplete monitoring and documenting of the laboratory refrigerator. The Medical Director indicated lab results collected and stored out-of-range from the recommended temperatures could result in inaccurate results.	V 675		
V 715	MD RESP-ENSURE ALL ADHERE TO P&P CFR(s): 494.150(c)(2)(i) The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers;	V 715		3/1/22

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This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, the medical director failed to ensure the facility followed policy regarding checking expiration dates of the glucose monitoring device control solutions, labeling of 1:10 and 1:100 bleach solution, ensuring an assessment was completed prior to the first treatment, and refreshing the saline in the bloodlines prior to patient connection per policy and procedure in 1 of 1 facilities observed, in 1 of 1 new admissions reviewed and 1 of 4 treatment initiations. (Patient 1)

Finding Include:

1. A policy titled "EmbracePro Blood Glucose Monitor: Quality Control" dated September 2020 was provided by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to, "Check high and low control solutions expiration date. Do not use control solutions past expiration date. Discard control solutions 90 days after opening or on the expiration date printed on the bottle, whichever comes first."

A policy titled "Infection Control for Dialysis Facilities" dated October 2021 was provided by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to "The expiration date will be checked on all disposable supplies before the package is opened and the contents are used. The contents of the packages will not be used beyond the expiration date on the package"

A policy titled "Preparation of One To Ten (1:10) Bleach Solution" dated April 2021 was provided

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by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to, "With indelible marking pen and label, label container with expiration date, time, and initials. The solution is good for 24 hours only." ... "The solution must be changed when the maximum allowable time is exceeded (24 hours) or when the solution becomes cloudy or turbid."

A policy titled "Preparation of One To One Hundred (1:100) Bleach Solution" dated April 2021 was provided by Employee A on 1/26/2022 at 9:00 a.m. The policy indicated but was not limited to, "With indelible marking pen and label, label container with expiration date, time, and initials. The solution is good for 24 hours only." ... "The solution must be changed when the maximum allowable time is exceeded (24 hours) or when the solution becomes cloudy or turbid."

A policy titled "New Patient Pre-Treatment Evaluation" dated October 2021 was provided by Employee A on 1/26/2022 at 12:55 p.m. The policy indicated but was not limited to, "1. A registered nurse (RN) as required by federal regulation will perform an initial pre-treatment evaluation for all patients prior to the initiation of their first treatment at the facility."

A policy titled "Treatment Initiation Utilizing Fresenius 2008 Series Dialysis Delivery Systems With All Single Use Dialyzer Types and Streamline or Combiset or Nipro Bloodlines" dated October 2021 was provided by Employee A on 1/26/2022 at 2:08 p.m. The policy indicated but was not limited to, "Open the clamp on the arterial line and flush for 25 seconds (approximately 50 ml of saline) through the arterial line." ... "Unclamp venous line, turn blood

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pump on and flush 250 ml of normal saline into priming container (which takes 38 seconds at a pump speed of 400 ml/min."

2. A document titled "New Patient Pre-Treatment" dated 12/28/2021 was provided by Employee A on 1/26/2022 at 9:49 a.m. The summarized document indicated but was not limited to an assessment completed by an RN on 12/28/2021 for Patient 1. The assessment was signed and dated by the RN but the time the assessment was completed was left blank. Unable to determine if assessment was completed prior to treatment or after treatment was started.

An interview was completed with Employee B on 1/26/2022 at 9:33 a.m. Employee B confirmed a time had not been documented into the RN assessment for Patient 1, new admission, and could not provide any further evidence this assessment was completed prior to the patients first treatment. Indicated that the registered nurse is supposed to complete consents and assessments prior to the first treatment.

3. During an observation on 1/25/2022 at 10:55 a.m. the Embrace Pro 2.5 ml bottle was found to have a manufacturer's expiration date of 1/1/2022 and a handwritten expiration date of 4/25/2021.

An interview was completed with Employee A and Employee B on 1/25/2022 at 1:23 p.m. Both employees were advised of the expired control solution for the glucometer found during the flash tour. Employee B indicated that a handwritten expiration date is placed on the bottle when opened. The handwritten date represents the expiration date of 90 days after initially opening the bottle.

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4. During an observation on 1/25/2022 at 11:22 a.m. the bleach solution marked 1:10 and 1:100 located at the nurse's station and again at the technician's station (4 in all) all had a handwritten marking on the containers indicating the date 1/27/2022 at 8:18 a.m.

An interview was completed with Employee J on 1/25/2022 at 12:32 p.m. Employee J agreed that the dates handwritten on the bleach containers displayed an expiration date > 24 hours. Indicated staff member responsible for making the bleach and labeling the bleach wrote the wrong date on the container. Unable to advise when bleach was made but did indicate that bleach was good for 48 hours, then corrected to 24 hours.

5. During an observation on 1/26/2022 at 10:48 a.m. Employee J was initiating treatment for Patient 12. Observed Employee J "refresh" (term used to drain saline solution in bloodlines and replace with fresh saline solution) the arterial blood line for approximately 3 seconds, then "refresh" the venous line for approximately 3 seconds prior to connecting the bloodlines to the access needles located in Patient 12's left arteriovenous fistula.

An interview was completed with Employee J on 1/26/2022 at 11:16 a.m. Employee J indicated the arterial line should be refreshed with 50 ml of saline and the venous line should be refreshed with 200-250 ml of solution taking approximately 40 seconds.