STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152646	A. BUILDING 00 B. WING	01/12/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
SCOTTSBURG DIALYSIS	1619 W MCCLAIN AVE SCOTTSBURG, IN 47170

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E 0000 Bldg. 00	An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62. Survey Dates: January 10th, 11th, & 12th of 2023 Facility ID: 012585 Census: In-Center Patients 18 Home Hemodialysis Patients 0 Peritoneal Dialysis Patients 0 At this Emergency Preparedness survey, Scottsburg Dialysis, was found in compliance with Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers, 42 CFR 494.62. QR completed on 1/26/2023 A4	E 0000	Found in compliance	
V 0000 Bldg. 00	This visit was for a federal core ESRD (Core) recertification survey. Survey Dates: January 10th, 11th, & 12th of 2023. Facility ID: 012585 Census: 18 In-Center Hemodialysis 0 Home Hemodialysis 0 Peritoneal Dialysis Record Reviews: 5	V 0000	Recertification Survey was completed.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Melissa Bowling	Facility Administrator	02/03/2023

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determin other safegaurds provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclo days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V 0122 Bldg. 00	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, record review, and interview, the facility failed to ensure all staff were following proper infection control procedures regarding hand hygiene to prevent the spread of infection and communicable diseases in 2 of 4 patients observed (PCT B and PCT A). Findings Include: 1. A policy titled, "Infection Control for Dialysis Facilities" revised in October 2020 indicated but was not limited to, "13. Gloves should be changed when:....When going from a dirty area or task to a clean area or task." 2, During an observation on 1/10/2023 at 10:25 a.m., PCT (Patient Care Technician) B was observed discontinuing treatment on Patient # 7, an AVF (arteriovenous fistula). After removing the patient's bloodlines from the inserted AVF needles, with gloved hands, PCT B picked up the biohazard container with both hands and moved it to the opposite side of Patient 7's chair. Without removing the dirty gloves, the PCT continued to pull both the venous and arterial needles from the patient's AVF.	V 0122	V122 The Facility Administrator or designee will in-service all clinical teammates on Policy 1-05-01 “Infection Control For Dialysis Facilities” beginning 1/12/23. Verification of attendance is evidenced by a signature sheet. Teammates will be instructed with emphasis on, but not limited to, the following: 1) Gloves should be worn when: …When going from a “dirty” area or task to a “clean” area or task…The Facility Administrator or designee will conduct observational audits daily for two (2) weeks, then weekly for two (2) weeks to verify compliance with facility policy beginning 2/6/23. Ongoing compliance will be verified monthly during internal infection control audits. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review audit results with teammates during Homeroom meetings and with the Medical	02/26/2023

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	3. During an observation on 01/10/2023 at 10:50 a.m. while cleaning and disinfecting dialysis station #4, PCT A removed the used bloodlines and disposable equipment and disposed of them in a biohazardous bin. PCT A then began wiping down the dialysis delivery system and other dedicated equipment. PCT A failed to change gloves or perform hand hygiene when moving from a dirty to a clean area. 4. During an interview on 1/10/2023 at 4:30 p.m., the facility administrator indicated the gloves should have been removed, hands sanitized, and clean gloves redonned. Indicated she would discuss these concerns observed with the staff.		Director during monthly Quality Assurance Performance Improvement meeting, known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction.	
V 0196 Bldg. 00	494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY 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			

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	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. Based on observation, record review, and interview, the facility failed to ensure that Total Chlorine testing was completed per policy in 1 of 1 observation. Findings Include: 1. A policy titled, Total Chlorine Test Using RPC Ultra Low Total Chlorine Test Strips" updated in April 2017 indicated, but was not limited to, "Procedure:" ... " Fill the sample cup to the line marked 100 ml (milliliters) with the sample." 2. During an observation on 1/12/2023 at 11:58 a.m.,. PCT (Patient Care Technician) B was observed collecting a sample of water in a small cup to complete Total Chlorine testing. PCT B indicated that there is no set amount of water that has to be tested using the RPC strips provided. Indicated she usually gets about this much water to test, lifting the sample cup to surveyor to view. Noted that there was 150 milliliters in the sample cup. PCT B was unable to locate the policy on this to verify. 3. During an interview 1/12/2023 at 12:03 p.m., the FA (facility administrator) stated she was not sure what the policy was regarding how much water to sample for the total chlorine test. The FA walked back to the water room with surveyor and pulled	V 0196	The Facility Administrator or designee will in-service all clinical teammates on Policy 2-05-02H "Total Chlorine Test Using RPC Ultra Low Total Chlorine Test Strip" beginning 1/12/23. Verification of attendance is evidenced by a signature sheet. Teammates will be instructed with emphasis on, but not limited to, the following: 1) Fill the sample cup to the line marked 100 ml with the sample. All clinical teammates responsible for testing dialysis quality water for total chlorine were re-educated on facility policy on 1/12/23. The Facility Administrator or designee will conduct observational audits of a teammate testing dialysis quality water for total chlorine daily for two (2) weeks, then weekly for two (2) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly x 3 months. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review audit results with teammates during Homeroom	02/26/2023

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	the policy that was hanging on the testing cart. Read that 100 milliliters of water were to be used for testing.		meetings and with the Medical Director during monthly Quality Assurance Performance Improvement meeting, known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction.	
V 0403 Bldg. 00	494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU 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. Based on observation, record review, and interview the facility failed to ensure malfunctioning machines and ancillary equipment were labeled or tagged to prevent use on the treatment floor for 1 of 1 facility reviewed. Findings include: 1. A 09/2013 revised policy titled "Dialysis Delivery System Failures Occurring During Treatment" was provided by the administrator on 01/12/2023 at 11:38 a.m. The document indicated but was not limited to: The dialysis delivery system is to be labeled with a description of the problem and the identity of the teammate describing the problem.	V 0403	The Facility Administrator or designee will in-service all clinical teammates, including biomedical teammates on Policy 2-01-04 “Dialysis Delivery System Failures Occurring During Treatment” and Policy 2-01-06 “Documentation of Repairs, Maintenance and Calibration On Equipment”. Verification of attendance is evidenced by a signature sheet. Teammates will be instructed with emphasis on, but not limited to, the following: 1) …the dialysis delivery system labeled with a description of the problem and identity of the teammate describing the problem. 2) The	02/26/2023

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	2. On 01/10/2023 the preventative maintenance documents for all facility equipment was provided by the Biomed H. The documents failed to evidence 2 of 3 infusion pumps had received their annual preventative maintenance. 3. During a flash tour observation on 01/10/2023 2 dialysis delivery systems were observed in a room without a tag identifying the machines as malfunctioning. A red tag was taped on one of the machines with the handwritten note "Ok to use." Outside of the room, a dry-erase board was evidenced with a note "Machine #5 won't go through heat disinfect." In the "Reuse" room 2 infusion pumps were observed. The two pumps had expired maintenance stickers and 1 pump had a tourniquet tied around the infusion pump pole. 4. During an interview on 01/10/2023 at 10:30 a.m. Patient Care Technician (PCT) A stated the 2 infusion pumps in the Reuse room were broken and the 1 infusion pump that was working was on the treatment floor. 5. During an interview on 01/10/2023 at 11:20 a.m. the administrator stated when a machine is pulled off the floor the issue is written on a dry-erase board, the Biomed technician is sent a text message, and a hanging tag is placed on the machine. They stated they believe it is a red tag but were unsure and would have to check. The administrator stated the same applied to infusion pumps. 6. During an interview on 01/10/2023, Biomed H stated the 2 machines in the room identified were malfunctioning and the 2 infusion pumps in the reuse room were broken and waiting on parts for repair.		labeled dialysis delivery system will be removed from the treatment area. for repairs. 3) …the dialysis delivery system will be labeled post treatment with a description of the problem and the identity of the teammate describing the problem. 4) All repairs, maintenance and calibrations performed by a trained Biomed teammate on any related dialysis equipment will be documented in BART within 72 hours. 5) All miscellaneous equipment will receive PM performed by trained Biomed teammate or outside vendor per manufacturer's recommendations. Examples of miscellaneous equipment may include, but are not limited to: …infusion pumps…The Facility Administrator or designee will conduct audits daily x 1 week, then weekly x 4 weeks to verify compliance with facility policy for repair and documentation of repair and preventative maintenance on dialysis equipment. Ongoing compliance will be verified with audits monthly x 3 months. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review audit results with teammates during Homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement meeting, known as Facility Health Meetings, with	

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			supporting documentation included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction.	
V 0503 Bldg. 00	494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX The patient's comprehensive assessment must include, but is not limited to, the following: (2) Evaluation of the appropriateness of the dialysis prescription, Based on record review and interview the facility failed to achieve the prescribed Blood Flow Rate (BFR) and failed to update the hemodialysis prescription for 1 of 5 patient records reviewed. (Patient #2) Findings include: 1. The treatment record for patient #2 was reviewed on 01/11/2023 and evidenced the following: A document titled "Treatment Details Report" dated 12/22/2022 evidenced a prescribed blood flow rate of 450 mL/min. The treatment BFR was set to 400 mL/min. A document titled "Treatment Details Report" dated 12/31/2022 evidenced a prescribed blood flow rate of 450 mL/min. The treatment BFR was set to 300 mL/min. A document titled "Treatment Details Report" dated 12/29/2022 evidenced a prescribed blood	V 0503	V 503 The Facility Administrator or designee will in-service all clinical teammates on Policy 1-03-08 "CWOW-Pre-Intra-Post Treatment Data Collection, Monitoring And Nursing Assessment". Verification of attendance is evidenced by a signature sheet. Teammates will be instructed with emphasis on, but not limited to, the following: 1) Patient…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 when the ordered rate is obtained after onset of treatment. 2) Prescription components include but are not necessarily limited to: … Blood flow rate…3) If the dialysis prescription is not being met (including dialysis flow rate or change to /inability to obtain	02/26/2023

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	flow rate of 450 mL/min. The treatment BFR was set to 425 mL/min. A document titled "Treatment Details Report" dated 01/03/2023 evidenced a prescribed blood flow rate of 450 mL/min. The treatment BFR was set to 380 mL/min. A document titled "Treatment Details Report" dated 01/05/2023 evidenced a prescribed blood flow rate of 450 mL/min. The treatment BFR was set to 400 mL/min. A document titled "Treatment Details Report" dated 01/07/2023 evidenced a prescribed blood flow rate of 450 mL/min. The treatment BFR was set to 365 mL/min. 2. During an interview with the administrator on 01/12/2023 at 9:10 a.m. they stated if staff is unable to achieve the patient's prescribed BFR there should be documentation indicating the reason and if it is a continuous problem the physician should have been notified.		prescribed blood flow rate) the reason will be documented and the licensed nurse informed. 4) All findings, interventions and patient response will be documented in the patient's medical record. The Facility Administrator or designee will audit 50% of Treatment Details Reports daily x 2 weeks, then weekly x 2 weeks to verify compliance with facility policy and dialysis prescription. Ongoing compliance will be verified with 10% of Treatment Details Reports audited monthly x 3 months during the internal medical record audit. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review audit results with teammates during Homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement meeting, known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction.	
V 0543 Bldg. 00	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and			

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	services to manage the patient's volume status; Based on record review and interview, the facility failed to ensure a written and/or verbal physician order was obtained authorizing fluid removal during hemodialysis greater than 13 mL/kg/hr. (milliliters per kilogram per hour) in 1 of 5 records reviewed (Patient #3). Findings Include: 1. An article titled, "Ultrafiltration Rate Thresholds in Maintenance Hemodialysis: An NKF-KDOI Controversies Report" dated 7/19/2016 found on https://pubmed.ncbi.nlm.nih.gov/27449697/ indicated, but was not limited to, "High hemodialysis ultrafiltration rate (UFR) is increasingly recognized as an important and modifiable risk factor for mortality among patients receiving maintenance hemodialysis. Recently, the Kidney Care Quality Alliance (KCQA) developed a UFR measure to assess dialysis unit care quality. The UFR measure was defined as UFR greater than or equal to 13 ml/kg/h for patients with dialysis sessions lengths less than 240 minutes and was endorsed by the National Quality Forum as a quality measure in December 2015." 2. An article titled, "Frequently High Ultrafiltration Rates in Dialysis May Up Death Risk" dated 5/11/2022, found on RenalandUrologyNews.com indicated, but was not limited to, "Among patients initiating hemodialysis (HD), those with a greater proportion of sessions with an ultrafiltration rate (UFR) higher than 13 ml/kg/hr may have greater risks for all-cause and cardiovascular death, a new study finds."	V 0543	The Facility Administrator or designee will in-service all clinical teammates on Policy 1-03-08 "CWOW-Pre-Intra-Post Treatment Data Collection, Monitoring And Nursing Assessment". Verification of attendance is evidenced by a signature sheet. Teammates will be instructed with emphasis on, but not limited to, the following: 1) Patient…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 when the ordered rate is obtained after onset of treatment. 2) Prescription components include but are not necessarily limited to: … UFR and Max UFR…A patient specific order was obtained from Patient #3's attending physician for an ultrafiltration rate greater than 13 ml/kg/hr with specified limits and when to notify the physician. The Facility Administrator or designee will audit 50% of Treatment Details Reports, to include Patient #3, daily x 2 weeks, then weekly x 2 weeks to verify compliance with facility policy and patient specific order for ultrafiltration rates during dialysis. Ongoing compliance will be verified with 10% of Treatment Details Reports, to include Patient #3, audited monthly x 3 months	02/26/2023

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	3. Treatment sheets dated 12/20/2022, 12/22/2022, 12/24/2022, 12/29/2022, 1/5/2023, and 1/7/2023 indicates a maximum UFR rate of 13 mL/kg/hr. 4. During a record review on 11/11/2023 Patient #3 treatment records revealed 6/8 treatments with an Ultrafiltration Rate (UFR) greater than or equal to 13 mL/kg/hr during hemodialysis as follows: 12/20/2022 UFR of 16.0 mL/kg/hr 12/22/2022 UFR of 15.8 mL/kg/hr 12/24/2022 UFR of 17.4 mL/kg/hr 12/29/2022 UFR of 16.1 mL/kg/hr 1/5/2023 UFR of 14.5 mL/kg/hr 1/7/2023 UFR of 15.4 mL/kg/hr 5. During an interview on 1/12/2023 at 9:04 a.m., the Facility Administrator (FA) indicated that she did not have a physician order for Patient #3 to complete treatments with a UFR greater than or equal to 13 mL/kg/hr on the above treatment dates, but has now obtained one for the clinical record.		during the internal medical record audit. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review audit results with teammates during Homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement meeting, known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction.	
V 0634 Bldg. 00	494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification. Based on record review and interview the facility failed include all adverse event data in their quality assurance monitoring program (FHM) for 1 of 1 adverse event reviewed. (Patient #2) Findings include: 1. The 2022 Adverse Events log was provided by	V 0634	V634 The Facility Administrator or designee will in-service all clinical teammates on Policy 113-01-02 “Risk Event Reporting Policy (Non-Teammate Related). Verification of attendance is evidenced by a signature sheet. Teammates will be instructed with	02/26/2023

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	the administrator on 01/12/2023 at 9:10 a.m. The document failed to show evidence of patient #2's dialyzer clotting in December of 2022. 2. The treatment record for patient #2 was reviewed on 01/11/2023 and evidenced the following: 3. A document titled "Treatment Details Report" dated 12/31/2023 for patient #2 that indicated, but was not limited to "Treatment terminated; blood clotted, pulled 3 (inch) clot from venous access; blood not returned." 4. During an interview on 1/12/2023 at 10:58 p.m. the administrator stated they verified and the adverse event for patient #2 was not listed in their adverse event log and stated the event should have been recorded in the log and included in their FHM.		emphasis on, but not limited to, the following: 1) Any unexpected event that is inconsistent with the routine operation of a dialysis facility, routine provision of acute dialysis or ancillary renal-related services may be a risk event. 2) All risk events will be promptly reported to the Facility Administrator/Manager or designee. 3) The teammate involved in the risk event or who witnessed the risk event firsthand will complete a Risk Event Management (REM) Report. 4) Risk Event Management (REM) Reports are to be trended and reviewed during the Facility Health Meeting (FHM). The Facility Administrator or designee will audit 50% of Treatment Details Reports and the adverse event log daily x 2 weeks, then weekly x 2 weeks to verify compliance with facility policy for reporting adverse patient events. Ongoing compliance will be verified with 10% of Treatment Details Reports and the adverse event log audited monthly x 3 months. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review audit results with teammates during Homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement meeting, known as Facility Health Meetings, with	

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			supporting documentation included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction.	
V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on observation, record review, and interview the facility failed to ensure medications and supplies were not expired in 1 of 1 dialysis facilities observed. Findings Include: 1. A policy titled, "Medication Policy," updated in October of 2022 indicated but was not limited to, "Do not use any ampule or vial that has been stored improperly or has expired" ... "Disposal of expired medications, including all over the counter and nutritional product samples are removed from the treatment and inventory areas and disposed of per state/local regulations." 2. During a flash tour on 01/10/2023 at 10:15 a.m. observation of the medication drawer evidenced 2 bottles of Cinncalot (a medication used to treat hyperparathyroidism, parathyroid carcinoma, and primary hyperparathyroidism) with a 2022 expiration date.	V 0715	V715 A Governing Body meeting will be conducted to review and discuss findings from the recent survey. The Governing Body will review Policy COMP-DD-017 “Medical Director Qualifications and Responsibilities” to include: 1) Medical Director responsibilities include, but are not limited to, the following…: …Oversight of 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…Verification of review will be evidenced by the Medical Director’s signature on the policy. The Facility Administrator or designee will in-service all teammates on Policy 1-06-01 “Medication Policy” and Policy	02/26/2023

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	3. During a flash tour on 01/10/2023 at 10:30 a.m. a bottle of expired conductivity solution was observed on the counter with an expiration date of 10/04/2022. 4. During an interview on 1/10/2023 at 10:15 a.m. the administrator stated the expired medications should have been removed from the drawer. 5. During an interview on 01/10/2023 at 2:52 p.m. the administrator stated they were unaware the conductivity solution had expired and it should have been removed from the treatment floor.		2-08-01A Calibration Check And Calibration Of Portable Myron L Conductivity Meter (D-1)". Verification of attendance is evidence by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) Do not use any ampule or vial that has been stored improperly or has expired. 2) Disposal of expired medications, including all over the counter and nutritional product samples are removed from the treatment and inventory areas and disposed of per state/local regulations. 3) Follow manufacturer's labeling of the solution for expiration dates. On 1/10/23, the Facility Administrator or designee removed and discarded the two (2) bottles of Cinacalcet from the medication drawer and removed and discarded the expired bottle of conductivity solution from the counter. The Facility Administrator or designee will conduct observational audits daily for two (2) weeks, then weekly for two (2) weeks to verify compliance with facility policy for expired medications and solutions. Ongoing compliance will be verified monthly during the internal audits. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review audit results with	

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			teammates during Homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement meeting, known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction	
V 0800 Bldg. 00	494.30 (b)(1)-(3)(i)-(x) COVID-19 Vaccination of Facility Staff § 494.30 Condition: Infection control. (b) COVID-19 Vaccination of facility staff. The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine. (1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients: (i) Facility employees; (ii) Licensed practitioners; (iii) Students, trainees, and volunteers; and (iv) Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other			

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	arrangement. (2) The policies and procedures of this section do not apply to the following facility staff: (i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section; and (ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section. (3) The policies and procedures must include, at a minimum, the following components: (i) A process for ensuring all staff specified in paragraph (b)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients; (iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19; (iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (b)(1)			

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	of this section; (v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC; (vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law; (vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements; (viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains: (A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and (B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications; (ix) A process for ensuring the tracking and secure documentation of the vaccination			

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	status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and (x) Contingency plans for staff who are not fully vaccinated for COVID-19. Effective 60 Days After Publication: (ii) A process for ensuring that all staff specified in paragraph (b)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations; Based on record review, and interview, the facility failed to ensure their COVID-19 Vaccination Policies and Procedures included additional precautions to be implemented to mitigate the spread of COVID-19 (infectious respiratory disease) for unvaccinated staff that provided direct patient care in the treatment area that went above standard precautions currently in place for 1 of 1 facility reviewed. Findings include: 1. A March 2022 policy titled Covid-19 Vaccination Policy for Dialysis Facilities and Programs was provided by the administrator on 01/12/2023 at 2:00 p.m. The policy indicated but was not limited to, "7. Contingency plan for	V 0800	V800 100% of clinical teammates were in-serviced on Policy 4-06-08 “COVID-19 Vaccination Policy for Dialysis Facilities and Programs”. Verification of attendance will be evidenced by a signature sheet. Teammates will be instructed using surveyor observations as examples with emphasis on, but not limited to, the following: 1) Contingency plan for teammates who are not fully vaccinated; teammates with approved exemptions, or who are not yet fully vaccinated, or who have a temporary delay will be required to	02/26/2023

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	teammates that are not fully vaccinated: ... abide by all applicable DaVita guidance related to COVID precautions (e.g., physical distancing, masking, screening, cleaning, and disinfection, etc.) and infection control policies and practices, (e.g., DaVita Breakroom Guidance which requires wearing a mask in breakroom when not eating, staggering teammate breaks to limit number of teammates in room at one time, and social distancing of 6 ft)." 2. During an interview with the FA (facility administrator) on 1/12/2023 at 2:40 p.m., the FA indicated that all employees follow CDC (Center for Disease Control and Prevention) guidelines in regards to COVID-19 prevention. No additional precautions are being implemented for employees that are not vaccinated to mitigate the spread of COVID-19.		abide by all applicable DaVita guidance related to COVID precautions (e.g., physical distancing, masking, screening, cleaning and disinfection, etc.) and infection control policies and practices (e.g., DaVita breakroom guidance which requires wearing a mask in breakroom when not eating, staggering teammate breaks to limit number of teammates in room at one time, and social distancing of 6 feet). Attachment N for ESRD facility for QSO-22-09-ALL memorandum revised on 4/5/22: Guidance for the Interim Final Rule- Medicare and Medicaid Programs: Omnibus COVID-19 Health Care Staff Vaccination states that “The policy must also ensure those staff who are not yet fully vaccinated, or who have been granted an exemption or accommodation as authorized by law, or who have a temporary delay, adhere to additional precautions that are intended to mitigate the spread of COVID-19. This requirement is not explicit and does not specify actions that must be taken; there are a variety of actions or job modifications that a facility may implement to potentially reduce the risk of COVID- 19 transmission, examples including but not limited to: Requiring staff who have not completed their primary vaccination series to follow	

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			additional, CDC recommended precautions, such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e. g. staff meeting rooms, kitchen)…." DaVita policy incorporates this requirement and goes above the CDC-recommended precautions for unvaccinated teammates. Because DaVita has unvaccinated teammates in the facility, all people (including unvaccinated teammates) who enter the facility are required to do a verbal attestation confirming lack of COVID-19 symptoms and must have his/her temperature taken and documented upon entry. Also all patients and teammates (including unvaccinated teammates) are required to wear a medical grade mask at all times while in the facility. Additionally, DaVita requires all teammates (including unvaccinated teammates) to undertake extra precautions when in the breakroom since this is a time when he/she will potentially be without a mask while eating and drinking. The additional precautions for the breakroom include social distancing, staggering breaks to minimize the number of people in the room at one time, and continuing to mask unless eating or drinking. All of these measures are additional	

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			precautions that DaVita requires of all teammates (including unvaccinated teammates) throughout its facilities in order to mitigate the spread of COVID-19. Currently, all teammates working in this facility have received COVID-19 vaccinations and the facility is in compliance with the "COVID-19 Vaccination Policy For Dialysis Facilities and Programs". In the event a teammate who is not vaccinated works in this facility, the facility will implement the applicable measures outlined in facility Policy 4-06-08 "COVID-19 Vaccination Policy For Dialysis Facilities and Programs". The Facility Administrator will review the COVID-19 vaccination status of facility teammates with the Medical Director during monthly Quality Assurance Performance Improvement meetings, known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for ongoing compliance with the Plan of Correction.	