

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 03/21/2023

FORM APPROVED

OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152652	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  03/02/2023
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NAME OF PROVIDER OR SUPPLIER  PAOLI DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP COD 555 WEST LONGEST STREET PAOLI, IN 47454
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
E 0000  Bldg. 00	<p>An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62.</p> <p>Survey Dates: 2/28/2023, 3/1/2023, 3/2/2023</p> <p>ICHD 12 month unduplicated census: 31</p> <p>Home Peritoneal Dialysis census: 3</p> <p>Home Hemodialysis census: 2</p> <p>Total: 36</p> <p>At this Emergency Preparedness survey, Paoli Dialysis, was compliance with the Emergency Preparedness requirements for Medicare and Medicaid Participating Providers and Suppliers for 42 CFR 494.62.</p> <p>QR Completed 3/10/2023 A4</p>	E 0000		
V 0000  Bldg. 00	<p>This visit was for a Federal recertification survey of an ESRD provider conducted by the Indiana Department of Health.</p> <p>Survey dates: 02-28, 03-01, 03-02-2023</p> <p>Facility ID: 012749</p> <p>ICHD 12 month unduplicated census: 31</p> <p>Home Peritoneal Dialysis census: 3</p>	V 0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Jessica Lueken	RN,FA	03/21/2023

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards 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 disclosed 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 0113 Bldg. 00	<p>Home Hemodialysis census: 2</p> <p>Total: 36</p> <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.</p> <p>Based on observation, interview, and record review, the agency failed to ensure hand hygiene was performed per the agency's policy by staff and patients as noted during 1 of 2 observation days. (Employees: Patient Care Technician (PCT) 1 (three observations), PCT 3 and the Facility Administrator) (Patients #: 9, 4, 6, 7, 14 and 3)</p> <p>Findings include:</p> <p>1. On 03-01-2023 at 2:10 PM, the Corporate Administrator provided a revised October 2022, DaVita policy titled, " Infection Control for Dialysis Facilities". The policy indicated but was not limited to, "... 1. Hand hygiene is to be performed upon entering the patient treatment area, prior to gloving, after removal of gloves, after contamination... before touching clean areas such as supplies...12. Gloves should be worn when: ...setting up dialyzers...handling blood lines...35. Patients are encouraged to wash their hands and access...prior to the initiation of dialysis and wash their hands after treatment...".</p> <p>2. On 03-01-2023 at 8:40 AM, Patient #9, a patient with a Central Venous Catheter (CVC), (a vessel inserted into a vein below the collar bone) was</p>	V 0113	<p>V113</p> <p>The Facility Administrator or designee will in-service all clinical teammates on Policy 1-05-01 "Infection Control For Dialysis Facilities" beginning 3/13/23. 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: 1) Hand hygiene is to be performed upon entering the patient treatment area, prior to gloving, after removal of gloves, after contamination with blood or other infectious material...before touching clean areas such as supplies...2) Gloves should be worn when: ...Setting up dialyzers...Touching the blood lines...3) Patients are encouraged to wash their hands and access...prior to the initiation of dialysis and wash their hands after treatment before leaving treatment area. 4) Stethoscopes will be disinfected with alcohol prep pad</p>	03/31/2023

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	<p>seated at station #8. Patient #9 completed their treatment and left the treatment floor. No hand hygiene was performed.</p> <p>3. On 03-01-2023 at 8:50 AM, Patient #4, a patient with a CVC was seated at station #3. Patient #4 completed their treatment and left the treatment floor. No hand hygiene was performed.</p> <p>4. On 03-01-2023 at 8:40 AM, Patient #6, a patient with a CVC was seated at station #1. Patient #6 completed their treatment and left the treatment floor. No hand hygiene was performed.</p> <p>5. On 03-01-2023 at 9:30 AM, Patient #7 was observed holding their Left Upper Extremity (LUE) with a gloved right hand. Once their treatment was complete, Patient #7 removed the glove from their hand, weighed themselves, used the facility thermometer and exited the treatment floor. No hand hygiene was performed.</p> <p>6. On 03-01-2023 at 9:45 AM, Patient #14 was observed holding their LUE with a gloved right hand. Once their treatment was complete, Patient #14 removed the glove from their hand and exited the treatment floor. No hand hygiene was performed.</p> <p>7. On 03-01-2023 at 2:00 PM, PCT #1 was observed discontinuing the dialysis treatment for Patient #15. Patient #15 had a CVC. PCT #1 failed to remove their gloves after reinfusing the patients blood and perform hand hygiene.</p> <p>8. On 03-01-2023 at 2:05 PM, Patient #3 was observed holding their RUE with a gloved left hand. Once their treatment was complete, Patient #3 removed the glove from their hand and exited the treatment floor. No hand hygiene was</p>		<p>and/or 1:100 (one to one hundred) bleach solution and if they are visibly contaminated with blood or body fluids should be disinfected with a 1:10 (one to ten) bleach solution. (5) If electronic thermometers...are used, measures will be taken to prevent cross contamination between patients...the device outercasing is wiped with an appropriate disinfectant before...using on another patient. The Facility Administrator or designee will conduct observational infection control audits daily for two (2) weeks starting on 3/13/2023 then weekly for two (2) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the internal infection control audit. Instances of non-compliance will be addressed immediately. The Facility Administrator will review audit results 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.</p> <p>3/31/23</p>		

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	<p>performed.</p> <p>9. On 02-28-2023 at 2:05 PM, the Facility Administrator (FA) was queried on infection control practices. The FA indicated patients and staff should wash hands prior to and after treatment. Staff should wash hands multiple times during a procedure. Staff should wear masks and shields when on the treatment floor. 10. During an observation on 3-01-2023 at 9:25 AM PCT #1 was observed at station #9. PCT #1 was observed discontinuing the dialysis treatment for Patient #7. PCT #1 documented on the keyboard then failed to perform hand hygiene before donning new gloves.</p> <p>11. On 3/1/23 at 5:27 AM, PCT #1 was observed providing patient care to Patient #10. After cleansing the patient's arm, PCT #1 was observed adjusting their mask without removing their gloves, then obtaining the patient's stethoscope for auscultation. PCT #1 failed to maintain infection control standards for use of gloves and hand hygiene when moving from clean to dirty while wearing gloves.</p> <p>12. On 3/1/23 at 5:50 AM, PCT #3 was observed silencing a pump alarm for Patient #4, without performing hand hygiene prior to donning gloves. PCT #3 then discarded their gloves, completed hand hygiene, and began typing. While typing, PCT #3 was observed wiping/rubbing both eyes with both hands, then immediately donned gloves and opening supplies without completing hand hygiene. PCT #3 failed to maintain infection control standards for use of gloves and hand hygiene when moving from clean to dirty and back to clean.</p> <p>13. On 3/1/23 at 6:34 AM, the FA was observed completing hand hygiene and donning gloves.</p>			

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V 0116 Bldg. 00	<p>The FA then removed the right glove and obtained alcohol wipe from the central cabinets without completing hand hygiene, cleaned a stethoscope with the alcohol wipe, and one gloved hand, then discarded the left glove and completed hand hygiene. The FA failed to maintain infection control standards for use of gloves and hand hygiene while cleaning dirty supplies.</p> <p>494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT</p> <p>Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.</p> <p>-- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.</p> <p>-- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.</p> <p>Based on observation, record review, and interview the agency failed to ensure equipment used between patients was properly cleaned as noted over 1 of 2 observation days. (Patient Care Technician, Employee: 1) (Patient: #7).</p> <p>Findings include:</p> <p>1. On 03-01-2023 at 2:10 PM, the Corporate Administrator provided a revised October 2022, DaVita policy titled, " Infection Control for</p>	V 0116	<p>V116</p> <p>The Facility Administrator or designee will in-service all clinical teammates on Policy 1-05-01 "Infection Control For Dialysis Facilities" beginning 3/13/23. Verification of attendance will be evidenced by a signature sheet. Teammates will be instructed using surveyor observations as examples with emphasis on, but</p>	03/31/2023	

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	<p>Dialysis Facilities". The policy indicated but was not limited to, "...26. Stethoscopes will be disinfected with alcohol prep pad...34. If electronic thermometers ...are used...the device outer casing is wiped with an appropriate disinfectant before being returned ... or using on another patient...".</p> <p>2. On 03-01-2023 at 6:20 AM, Patient Care Technician (PCT) #1 utilized the stethoscope at Station #7 to auscultate the access of Patient #7. After use PCT #1 hung the stethoscope on the dialysis machine and did not disinfect the stethoscope.</p> <p>3. On 03-01-2023 during treatment floor observations from 5:00 AM through 7:50 AM, the thermometer used by the staff to monitor patients prior to and after dialysis treatments was used with and without gloves on staff. There was no cleaning of the thermometer between use on patients.</p> <p>4. On 03-01-2023 during treatment floor observations from 8:45 AM through 10:50 AM, the thermometer used by the staff to monitor patients prior to and after dialysis treatments was used with and without gloves on staff. There was no cleaning of the thermometer between use on patients.</p> <p>5. On 03-01-2023 at 9:30 AM, Patient #7 was observed leaving the treatment floor following their dialysis treatment. Patient #7 utilized the thermometer at the scale to check their temperature, weighed themselves and exited the treatment floor. The thermometer was not cleaned after use.</p> <p>6. On 03-01-2023 at 1:50 AM, the Corporate Administrator was queried on infection control</p>		<p>not limited to: 1) Stethoscopes will be disinfected with alcohol prep pad and/or 1:100 (one to one hundred) bleach solution and if they are visibly contaminated with blood or body fluids should be disinfected with a 1:10 (one to ten) bleach solution. 2) If electronic thermometers...are used, measures will be taken to prevent cross contamination between patients...the device outercasing is wiped with an appropriate disinfectant before...using on another patient. The Facility Administrator or designee will conduct observational infection control audits daily for two (2) weeks starting on 3/13/2023 then weekly for two (2) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the internal infection control audit. Instances of non-compliance will be addressed immediately. The Facility Administrator will review audit results 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.</p> <p>3/31/23</p>	

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V 0122 Bldg. 00	<p>practices. The Corporate Administrator indicated the stethoscopes and thermometers should be cleaned after use and if visibly soiled. Gloves should not be worn when using the thermometer.</p> <p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, record review, and interview, the agency failed to ensure the dialysis stations were properly disinfected after use as observed during 2 of 2 observation days. (Employee: Patient Care Technician # 2, 3 and Registered Nurse #1).</p> <p>Findings include:</p> <p>1. On 03-01-2023 at 2:10 PM, the Corporate Administrator provided a revised October 2022, DaVita policy titled, "Infection Control for Dialysis Facilities". The policy indicated but was not limited to, "...46. Equipment including the dialysis delivery system, the interior and exterior of the prime container, the dialysis chair, side tables including opening the chair to reach crevices, ...television arms and control...all work surfaces will be wiped clean with a bleach solution...".</p> <p>2. On 03-01-2023 at 8:45 AM, Patient Care Technician (PCT) #2 was observed cleaning</p>	V 0122	<p>V122 The Facility Administrator or designee will in-service all clinical teammates on Policy 1-05-01 "Infection Control For Dialysis Facilities" beginning 3/13/23. 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: 1) Equipment including the dialysis delivery system, the interior and exterior of the prime container, the dialysis chair and side tables including opening the chair to reach crevices,...television arms and control knobs or remote control devices...as well as all work surfaces will be wiped clean with a bleach solution of the appropriate strength after completion of</p>	03/31/2023

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	<p>dialysis station #8 once the treatment for Patient #9 had their blood returned to them. PCT #2 began to clean the dialysis machine, prime container and hoses while PCT #1 held pressure to the access site of Patient #9.</p> <p>3. On 03-01-2023 at 9:10 AM, PCT #3 was observed cleaning dialysis station #3. Patient #4 remain seated while awaiting a final blood pressure check. PCT #3 began to clean the dialysis machine while Patient #4 remained in their chair.</p> <p>4. On 03-01-2023 at 9:20 AM, PCT, Registered Nurse #1 brought a clean set up supplies to station #1 and began to setup the machine for the next patient. Station #1's chair, TV and chase walls had not been cleaned prior to set up.</p> <p>5. On 03-01-2023 at 11:39 AM, the Corporate Administrator was queried on the process of cleaning the station prior to use by another patient. The Corporate Administrator indicated the chair should be vacated prior to use.</p> <p>6. On 2/28/23 at 9:34 AM, a flash tour was conducted during entrance to the facility. The surveyor noted 2 boxes of non-sterile gloves under a chair and directly on the floor of the breakroom. During the end of day conference on 3/1/23 at 2:38 PM, the boxes were still present on the floor under the chair and were indicated to the Facility Administrator, who indicated gloves should not be stored on the floor.</p>		<p>procedures, before being used on another patient, after spills of blood, throughout the work day, and after each treatment. 2) 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. 3) Teammates will not store extra dialysis supplies...where contamination of such supplies could possibly occur. 4) Supplies will not be stored directly on the floor... The Facility Administrator or designee will conduct observational infection control audits daily for two (2) weeks starting on 3/13/2023 then weekly for two (2) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the internal infection control audit. Instances of non-compliance will be addressed immediately. The Facility Administrator will review audit results 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</p>	

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V 0147 Bldg. 00	<p>494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.</p> <p>II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>Based on observation, record review, and</p>	V 0147	<p>compliance with the Plan of Correction. 3/31/23</p>	03/31/2023

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	<p>interview the agency failed to maintain the proper care and treatment of the Central Venous Catheter (CVC) for patients as noted during the 1 of 1 treatment floor observation days. (Employee: Patient Care Technician (PCT) # 3 and #2).</p> <p>Findings include:</p> <p>1. On 03-01-2023 at 2:10 PM, the Corporate Administrator provided a revised October, 2022 DaVita policy titled, "Central Venous Catheter (CVC) HD Antimicrobial End Caps Procedure". The policy indicated but was not limited to, "...3. Verify patient's clothing is secured away from the exit site/work area...".</p> <p>2. On 03-01-2023 at 9:35 AM, PCT #3 - was observed cleaning the Central Venous Catheter (CVC) (a vessel inserted into the vein below the collar bone) insertion site of Patient #6 -. PCT #3 removed their gloves after removing the old dressing, performed hand hygiene and donned a new pair of gloves. The glove on the left hand little finger was not fully applied leaving a part dangling. When cleaning the hubs of the CVC lumens, the left hand little finger glove came into contact with the insertion site two times during the cleaning of the hubs.</p> <p>3. On 03-01-2023 at 1:50 PM, the Corporate Administrator was queried on the process of cleaning a CVC. The Corporate Administrator indicated the insertion site should not come into contact with anything. 4. During an observation on 3-01-2023 at 10:28 AM PCT #2 was observed discontinuing the dialysis treatment for Patient #8. Patient #8 had a CVC. PCT #2 reinfused the extracorporeal circuit, doffed gloves, performed hand hygiene, then began typing on a keyboard. PCT #2 failed to perform hand hygiene following</p>		<p>The Facility Administrator or designee will in-service all clinical teammates on Policy 1-04-02B "Central Venous Catheter (CVC) With CLEARGUARD HD Antimicrobial End Caps Procedure" and Policy 1-05-01 Infection Control For Dialysis Facilities" beginning 3/13/23. 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: 1) Verify patient's clothing is secured away from the exit site/work area. 2) Hand hygiene is to be performed...prior to gloving... The Facility Administrator or designee will conduct observational infection control audits daily for two (2) weeks starting on 3/13/2023 then weekly for two (2) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the internal infection control audit. Instances of non-compliance will be addressed immediately. The Facility Administrator will review audit results 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</p>	

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V 0402 Bldg. 00	<p>the use of the keyboard before applying new gloves and returning to the patient to disinfect the CVC hubs.</p> <p>494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY</p> <p>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. Based on observation, record review, and interview the facility failed to ensure the proper storage of medicines and supplies as noted over 2 of 3 survey days.</p> <p>Findings include:</p> <p>1. On 03-02-2023 at 9:05 AM, the Corporate Administrator provided a revised April 2018, DaVita policy titled, "Physical Environment". The policy indicated but was not limited to, "...2. The building in which dialysis services are furnished will be constructed and maintained for the safety of the patients, the teammates and the public...".</p> <p>2. On Tuesday, 02-28-2023 at 9:17 AM, during the Flash Tour 2 large cardboard boxes holding Styrofoam cups and 2 boxes of Centurion gloves were located on the breakroom floor. The treatment floor med drawers and cabinets holding Venofer (an iron supplement), Hectorol (medicine used to treat high levels of parathyroid hormone (PTH), Tylenol, Calcitriol (a calcium supplement), Clonidine (to treat high blood pressure), Benadryl (an antihistamine), TUMS, Cefazolin IV (an antibiotic given in the veins) were unlocked. The facility hours consisted of Monday, Wednesday, and Friday treatment days. A cardboard box with metal pieces near storage racks were stored on the</p>	V 0402	<p>compliance with the Plan of Correction. 3/31/23</p> <p>V402 The Facility Administrator or designee will in-service all clinical teammates on Policy 8-04-01 Physical Environment", Policy 1-05-01 "Infection Control For Dialysis Facilities", and Policy 1-06-01 "Medication Policy" beginning 3/13/23. 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: 1) The building in which dialysis services are furnished will be constructed and maintained for the safety of the patients, the teammates and the public. 2) The dialysis facility will store supplies in a manner that is consistent with fire safety and other appropriate regulations. 3) Supplies are stored as to minimize...contamination...4) Supplies will not be stored directly on the floor but stored on shelves or pallets...5) All refrigerated medications...are to be locked at</p>	03/31/2023	

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	<p>floor of the women's bathroom. Within the nurses station, the clean sink had bubble wrap packing under the sink. Under the "dirty" sink, a cardboard box storing a vase was present.</p> <p>3. On Wednesday, 03-01-2023 at 5:00 AM, the medication cabinets on the treatment floor remained unlocked. The clean and dirty sink cabinets remained full of supplies. The cardboard boxes in the breakroom and bathroom remained on the floor.</p> <p>4. On 03-01-2023 at 1:50 PM, the Facility Administrator (FA) was queried about the cleaning process of the treatment floor after hours. The FA indicated the facility is cleaned by an external entity on Tuesdays and Thursdays making the medication drawers accessible. The FA indicated the drawers should have been locked.</p>		<p>the close of each business day or if not under supervision by the licensed teammate or per state regulations. 6) Non-refrigerated medications are to be stored in cabinet(s) and locked at the close of each business day or if not under supervision by the licensed teammate or per state regulations. The Facility Administrator or designee removed the two (2) large cardboard boxes containing styrofoam cups and gloves found on the breakroom floor, the one (1) cardboard containing metal pieces found on the floor in the women's bathroom, the bubble wrap under the "clean" sink at the nurses' station, and the cardboard box containing a vase under the "dirty" sink at the nurses' station and placed the all of the items in the appropriate storage area. The medications in the medication drawers and cabinet were secured to prevent unauthorized access. The Facility Administrator or designee will conduct observational audits of the physical plant daily x 2 weeks, then weekly x 2 weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the internal OSHA/safety audit. instances of non-compliance will be addressed immediately. The Facility Administrator will review audit results with the Medical Director during monthly Quality Assurance</p>	

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V 0800  Bldg. 00	<p>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.</p> <p>(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:</p> <p>(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 arrangement.</p> <p>(2) The policies and procedures of this section do not apply to the following facility</p>		<p>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.</p> <p>3/31/23</p>	

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	<p>staff:</p> <p>(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</p> <p>(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.</p> <p>(3) The policies and procedures must include, at a minimum, the following components:</p> <p>(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;</p> <p>(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;</p> <p>(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (b)(1) of this section;</p> <p>(v) A process for tracking and securely documenting the COVID-19 vaccination</p>			

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	<p>status of any staff who have obtained any booster doses as recommended by the CDC;</p> <p>(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;</p> <p>(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;</p> <p>(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:</p> <p>(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</p> <p>(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;</p> <p>(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical</p>			

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	<p>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.</p> <p>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 observation, record review, and interview, the agency failed to ensure COVID pandemic vaccination exemption requirements related to personal protective equipment were maintained for 2 of 2 employees citing religious exemptions. (Employee: Patient Care Technician (PCT) #1 and 3)</p> <p>Findings include:</p> <p>1. On 03-02-2023 at 9:05 AM, the Corporate Administrator provided a revised March 2022, DaVita policy titled, "COVID-19 Vaccination Policy for Dialysis Facilities and Programs". The policy indicated but was not limited to, "... b. Religious Exemption Requests (sic) shall include: i. A signed and dated statement from the teammate describing how compliance with the COVID-19 vaccination requirements conflicts... 7. Contingency plan for teammates ... teammates with approved exemptions...will be required to</p>	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 abide by all applicable DaVita guidance related to COVID precautions (e.g., physical distancing, masking, screening,	03/31/2023	

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	<p>abide by all applicable DaVita guidance related to COVID-19 precautions (e.g., physical distancing, masking...wearing a mask in breakroom...and social distancing of 6 ft).</p> <p>2. On 03-1-2023 during observations from 5:00 AM - 2:30 PM, it was noted Patient Care Technicians (PCT) (Employee # 1 and 3) wore the same surgical face masks as all employees. When off the treatment floor the employees did not wear a mask of any kind and did not practice social distancing of 6 feet or more.</p> <p>3. On 03-01-2023 at 10:03 AM, the Facility Administrator (FA), Employee #1, provided the personnel records of Employee #1 and #3 indicating their religious exemptions were approved by the agency. There was no other documentation provided. Corporate Administrator #1 indicated they do not have access to the attestation records regarding exemptions for employees.</p>		<p>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 additional, CDC recommended precautions, such as adhering to universal source control and physical distancing measures in</p>	

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			<p>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 precautions that DaVita requires of all teammates (including unvaccinated teammates) throughout its facilities in order to</p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

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			mitigate the spread of COVID-19. The Facility Administrator (FA) or designee will conduct a COVID-19 Field Audit Tool weekly x 4 to verify that all teammates including unvaccinated teammates are following the policy. Results of audits will be reviewed with Medical Director during monthly Quality Assurance Performance Improvement (QAPI), known as the Facility Health Meeting (FHM). The FA is responsible for ongoing compliance with this Plan of Correction (POC). 3/31/23		