

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

PRINTED: 03/13/2023

FORM APPROVED

OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152689	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 02/21/2023
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NAME OF PROVIDER OR SUPPLIER TERRE HAUTE DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP COD 504 6TH STREET TERRE HAUTE, IN 47807
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E 0000 Bldg. 00	An Emergency Preparedness Survey was conducted by the Indiana State Department of Health in accordance with 42 CFR 494.62. Survey Dates: 2/20/2023-2/21/2023 Census: 136 At this Emergency Preparedness survey, Terre Haute Dialysis was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. QR Completed 2/28/2023 A4	E 0000		
V 0000 Bldg. 00	This visit was for a Federal complaint survey of an ESRD Provider. Survey Dates: 2/20/2023-2/21/2023 Complaint: IN00399842-substantiated. Federal and State deficiencies were cited. Unrelated deficiencies were cited. Census: In-Center HD: 70 In-Center PD: 66 Total Census: 136 Isolation Room/Waiver: 1 Isolation Room	V 0000		
V 0111	494.30 IC-SANITARY ENVIRONMENT			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Angela Richey	Facility Administrator	03/08/2023

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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Bldg. 00	<p>The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>Based on observation, record review, and interview, the facility failed to ensure a sanitary environment was maintained to minimize the spread of infectious agents regarding treatment chairs with tape residue for 13 of 13 treatment chair observations (Treatment chairs); and failed to ensure employee face shields were stored and maintained in a sanitary manner for 1 of 2 observation days. (PCT 1)</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. A revised 10/2022 policy titled Infection Control for Dialysis Facilities was provided by the FA (Facility Administrator) on 2/20/2023 at 2:00 p.m. The policy indicated, but was not limited, "To minimize the spread of infections or bloodborne pathogens in the dialysis facility environment. ...7. ... applying cosmetics ... prohibited in the patient care area. 2. A revised 04/2018 policy titled Physical Environment was provided by the FA (Facility Administrator) on 2/21/2023 at 8:10 a.m. The policy indicated, but was not limited to. "3. While in the treatment area where patient care remains the primary focus, personal use of pagers, cell phones, iPods, MP3 players, etc. by teammates is not permitted." 3. During an observation on 2/20/2023 at 10:00 a.m. PCT 1 (Personal Care Technician) disposable face shield was observed lying directly on the counter in a designated clean area next to clean 	V 0111	<p>The Facility Administrator or designee will in-service all clinical teammates on Policy 1-05-01 "Infection Control For Dialysis Facilities" and Policy 8-04-01 "Physical Environment" beginning 2/21/23. Verification of attendance is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) PURPOSE: To minimize the spread of infections or bloodborne pathogens in the dialysis facility environment. 2) ...applying cosmetics...is prohibited in the patient care area. 3) While in the treatment area where patient care remains the primary focus, personal use of pagers, cell phones, iPods, MP3 players, etc. by teammates is not permitted. 4) The dialysis facility will implement and maintain a program to verify that all equipment... maintained...in accordance with the manufacturer's recommendations. 5) Clean areas should be clearly separated from contaminated areas. All dialysis (13) chairs were cleaned on 2/28/23 with removal of all white tape from the side trays. The Facility</p>	02/28/2023

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V 0113 Bldg. 00	<p>blue clamps. Personal lotion and 1 (one) cell phone were located on a counter in a designated clean area.</p> <p>4. During the treatment floor observation on 2/20/2023 between 9:30 a.m. to 10:00 a.m. all 13 treatment chairs had white tape residue stuck to the side trays. The facility failed to ensure tape residue was removed from all treatment chair trays to minimize the spread of infectious agents between patients. At that time, RN 1 indicated staff had tried everything to remove the tape residue.</p> <p>5. During an interview on 2/20/2023 at 11:45 a.m. the FA and MD (Medical Director) indicated the face shield should be hanging in the designated area away from clean items and would look into the tape residue on the trays of the treatment chairs. The FA was unable to provide a specific policy regarding the removal of tape residue from the treatment chairs.</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, record review, and interview, the facility failed to ensure clean tape was applied to a patient's CVC (Central Venous Catheter) site for 1 of 1 CVC exit care observations. (PCT 1)</p> <p>Findings include:</p> <p>A revised 10/2022 policy titled Infection Control for Dialysis Facilities was provided by the FA</p>	V 0113	<p>Administrator or designee will conduct observational audits daily x 2 weeks, then weekly x 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 teammates during homeroom meetings and 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>The Facility Administrator or designee will in-service all clinical teammates on Policy 1-05-01 "Infection Control For Dialysis Facilities" and Policy 1-04-02A "Central Venous Catheter (CVC) With TEGO Connectors or CVC End Caps" beginning</p>	02/24/2023

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	<p>(Facility Administrator) on 2/20/2023 at 2:00 p.m. The policy indicated, but was not limited, "To minimize the spread of infections or bloodborne pathogens in the dialysis facility environment."</p> <p>During an observation on 2/20/2023 at 10:57 a.m. PCT 1 tore off 4 strips from a paper tape roll and applied each strip directly to the patient 8's treatment chair tray at station 7 while RN 1 was present. PCT 1 proceeded to perform CVC exit site care, applied sterile gauze over the CVC site, then applied each strip of barrier paper tape directly to patient 8's skin to secure the gauze dressing. PCT 1 failed to ensure clean paper tape was applied to patient 8's skin.</p> <p>During an interview on 2/20/2023 at 11:45 a.m. FA indicated that barrier tape that was applied directly to the treatment chair should not be used on the patient's skin. The FA was unable to provide a specific policy regarding how to use tape in a sanitary manner.</p>		<p>2/21/23. Verification of attendance is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) PURPOSE: To minimize the spread of infections or bloodborne pathogens in the dialysis facility environment. 2) Clean areas should be clearly separated from contaminated areas...3) ADDITIONAL NOTES: Use Dialysis Precautions and aseptic technique throughout procedure. The Facility Administrator or designee will conduct observational infection control audits daily x 2 weeks, then weekly x 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 teammates during homeroom meetings and 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</p>	

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V 0117 Bldg. 00	<p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS</p> <p>Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.</p> <p>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.</p> <p>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.</p> <p>Based on observation, record review, and interview, the facility failed to ensure personal cell phones were kept out of the treatment area for 1 of 2 observation days.</p> <p>Findings include:</p> <p>A revised 04/2018 policy titled Physical Environment was provided by the FA (Facility</p>	V 0117	<p>Administrator is responsible for ongoing compliance with the Plan of Correction.</p> <p>The Facility Administrator or designee will in-service all clinical teammates on Policy 8-04-01 "Physical Environment" beginning 2/21/23. Verification of attendance is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with</p>	02/24/2023

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V 0403 Bldg. 00	<p>Administrator) on 2/21/2023 at 8:10 a.m. The policy indicated, but was not limited to. "3. While in the treatment area where patient care remains the primary focus, personal use of pagers, cell phones, iPods, MP3 players, etc. by teammates is not permitted."</p> <p>During an observation on 2/20/2023 between 9:30 a.m. and 10:00 a.m. personal cell phones were located next to a designated clean computer area. One personal cell phone was connected directly to the computer terminal with a cord. Two small speakers playing music were located in a designated clean area on top of a counter. At that time, RN 1 was unsure who the speakers belonged to. RN 1 indicated staff uses the speakers to play music for the patients.</p> <p>During an interview on 2/21/2023 at 11:45 a.m. the FA indicated staff was using their own phones because the facility phones were down briefly. The FA indicated staff use their phones to play music for the patients, but agreed personal phones should not be in the treatment area.</p> <p>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</p>		<p>emphasis on, but not limited to the following: 1) While in the treatment area where patient care remains the primary focus, personal use of pagers, cell phones, iPods, MP3 players, etc. by teammates is not permitted. 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. Ongoing compliance will be verified monthly. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review the results of the audits with teammates during homeroom meetings and with the Medical Director during monthly Quality Assurance and Performance Improvement meetings known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for compliance with this plan of correction.</p>	

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	<p>manufacturer's recommendations.</p> <p>Based on observation, record review, and interview, the facility failed to accurately monitor and maintain the water softener equipment and allowed the brine tank to lack salt pellets to the manufactures required level for 1 of 1 brine tank observation with the potentially affecting the health and well-being of all 70 in-center hemodialysis patients.</p> <p>Findings include:</p> <p>During the water room flash tour on 2/20/2023 at 9:40 a.m. along with the FA (Facility Administrator) revealed the salt pellet level of the brine tank (water softener) to be a least 2 inches below water level. The manufacture label adhered to the brine tank indicated the salt level was to be above water level in the brine tank.</p> <p>A document titled Daily Water Treatment Log located in the treatment area on 2/21/2023 at 11:00 a.m. indicated, "Salt level in brine tank? Tank at least half full Y or N."</p> <p>During an interview on 2/21/2023 at 8:10 a.m. the FA indicated there was no policy for the brine tank and it was best practice for the salt pellets to be above the water level in the brine tank.</p> <p>During an interview on 2/21/2023 at 9:50 a.m. the BioMed personnel indicated it was a recommendation that salt pellets be above the water line and it would affect the membranes of the RO (Reverse Osmosis), but it presents no harm to the patient if the salt pellets were below the water level. BioMed indicated there was no policy for the brine tank and no manufacture guidelines were provided for review.</p>	V 0403	<p>The Facility Administrator or designee will in-service all clinical teammates on Policy 8-04-01 "Physical Environment" and Manufacturer Brine Tank Label beginning 2/21/23. Verification of attendance is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) The dialysis facility will implement and maintain a program to verify that all equipment, including ...the water treatment systems are maintained and operated in accordance with the manufacturer's recommendations. 2) VERIFY SALT LEVEL IS ABOVE WATER IN BRINE TANK. On 2/20/23, salt pellets were added to the Brine tank to raise the level of salt above the water level in the tank. The Facility Administrator or designee will conduct observational audits daily x 2 weeks, then weekly x 2 weeks to verify the level of salt in the Brine tank is above the water level per Manufacturer's guidelines. Ongoing compliance will be verified monthly. Instances of non-compliance will be addressed immediately. The Facility Administrator or designee will review the results of the audits with teammates during homeroom meetings and with the Medical</p>	02/24/2023

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V 0715 Bldg. 00	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must-</p> <p>(2) Ensure that-</p> <p>(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;</p> <p>Based on record review and interview, the facility failed to ensure policy and procedure was followed regarding medical record access for 1 of 5 records reviewed (Patient 1); and failed to ensure Kardex's contained accurate and current information regarding medications for 3 of 7 patient records reviewed which has the potential to affect all patients. (Patient 1, 3, 5)</p> <p>Findings include:</p> <p>1. A revised 04/2020 policy titled Transplant Referral and Tracking Process was provided by the FA (Facility Administrator) on 2/20/2023 at 11:45 a.m. The policy indicated, but was not limited to, "13. When a patient is referred to a transplant center, the Social Worker will track and document within the assessment progress notes, Plan of Care, notes, ... as to the status of the patient in the evaluation process and status as an</p>	V 0715	<p>Director during monthly Quality Assurance and Performance Improvement meetings known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for compliance with this plan of correction.</p> <p>A Governing Body meeting with the Medical Director, Facility Administrator and Regional Operations Director was held and reviewed the results of the survey ending on 3/3/23. The Governing Body reviewed Policy COMP-DD-017 "Medical Director Qualifications and Responsibilities" to include the following: 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, including attending physicians and</p>	03/15/2023

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	<p>active or inactive patient on the referring center's transplant list. Any barriers to the patient's transplant eligibility should be addressed with the patient by the IDT. ... 16. ... It is the Social Worker's or designee's responsibility to present education on transplant centers' contraindications and other factors that could affect the patient's chance to be listed, but the social worker should be supportive if the patient is still interested in pursuing transplant despite possible challenges. ..."</p> <p>2. A revised 10/2020 policy titled Patient Grievance was provided by the FA on 2/20/2023 at 11:45 a.m. The policy indicated, but was not limited to, "E. ... The Divisional Vice President will issue a written, final decision to the patient within 10 days of the grievance conference."</p> <p>3. A revised 04/2021 policy titled Continuous Quality Improvement Program was provided by the FA on 2/21/2023 at 8:30 a.m. The policy indicated, but was not limited to, "Purpose: To improve patient safety and outcomes including the reduction of medical errors."</p> <p>4. The clinical record for patient 1 was reviewed on 2/20/2023 and evidenced a signed Patient Rights document dated 7/5/2021. The document indicated, but was not limited to, "25. To receive a copy of my medical records. All requests for medical records will be put in writing. Based on individual state requirements for accessing medical records, there may be a fee charged for copying the medical records. All records requests will be completed within 30 days of the request."</p> <p>Review of the Complaint Logbook indicated patient 1 requested his/her medical record dated 11/4/2022 for review.</p>		<p>non-physician providers Verification of attendance and understanding will be evidenced by his/her signature on the policy. The Facility Administrator will in-service all teammates on Policy 1-14-08 "Transplant Referral And Tracking Process", Policy 3-01-06 "Patient Grievance", policy 3-01-07A "Patient's Rights", and Policy 1-06-01 "Medication Policy". Verification of attendance is evidenced by a signature sheet. Teammates were instructed using surveyor observations as examples with emphasis on, but not limited to the following: 1) When a patient is referred to a transplant center, the Social Worker will track and document within the assessment progress notes, Plan of Care, notes... as to the status of the patient in the evaluation process and status as an active or inactive patient on the referring center's transplant list. 2) Any barriers to the patient's transplant eligibility should be addressed with the patient by the IDT. 3) It is the Social Worker's or designee's responsibility to present education on transplant centers' contraindications and other factors that could affect the patient's chance to be listed, but the social worker should be supportive if the patient is still interested in pursuing transplant despite possible challenges. 4) If the patient grievance cannot be</p>	

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	<p>Review of the Authorization to Release Protected Health Information form indicated patient 1 completed the form dated 11/8/2022. The MSW indicated the form was faxed to the legal department the same day.</p> <p>Review of an email dated 12/14/2022 from HIM 1 (Health Information Management) indicated a request of patient 1's medical record. The email indicated, but was not limited to, "We must receive copies of the documents within seven (7) days of this email. HIPPA compliance requires DaVita to release records within 30 days of receipt of request. The department needs time to review and compile the records prior to release."</p> <p>Review of the fax cover sheets provided by the MSW on 2/21/2023 at 8:40 a.m. indicated patient 1's medical record was provided to HIM1 on 12/14/2022.</p> <p>Review of the fax document indicated the legal department sent patient 1's medical record by certified mail on 01/31/2023, 54 days late.</p> <p>During an interview on 2/21/2023 at 8:40 a.m. MSW (Master of Social Work) explained that when a patient requests his/her medical record, staff are required to complete a form with the patient's signature. The form was to be forwarded to DaVita legal department. The legal department has the facility to forward the patient's medical record to the legal department for review. The legal department then sends the medical record by certified mail to the patient. The MSW indicated the legal department has 30 days from when the form was completed to send the medical record to the patient. The MSW agreed patient 1 did not receive his/her requested medical records within</p>		<p>resolved by the ROD and/or Medical Director, the Divisional Vice President will be notified. 5) The Divisional Vice President will discuss the grievance with the patient and take appropriate action towards a solution. 6) The Divisional Vice President will issue a written, final decision to the patient within 10 days of the grievance conference. 7) To receive a copy of my medical records. All requests for medical records will be put in writing. Based on individual state requirements for accessing medical records, there may be a fee charged for copying the medical records. All records requests will be completed within 30 days of the request. 8) Medication orders must include the...frequency...date and time the order was received. The Facility Administrator or designee will audit medical records for patients referred for transplant monthly x 6 months to verify to verify documentation by the Social Worker of the patients' evaluation process, status and communication with the patients regarding any barriers to the patient's transplant eligibility. The Facility Administrator or designee will audit patient grievances weekly x 4 weeks, then monthly x 3 months to verify compliance with facility policy for patient grievances. The Facility</p>	

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V 0800 Bldg. 00	<p>the 30 day time frame.</p> <p>5. Review of patient 1's Kardex indicated an order for Mircera (medication for low red blood count) 50 mcg micrograms) IV Intravenous) push "[every 4]". The facility failed to indicate an accurate frequency for Mircera.</p> <p>6. Review of patient 3's Kardex indicated an order for Mircera 50 mcg IV push "e2". The facility failed to indicate an accurate frequency for Mircera.</p> <p>7. Review of patient 5's Kardex indicated an order for Mircera 50 mcg IV push "e4". The facility failed to indicate an accurate frequency for Mircera.</p> <p>8. During an interview on 2/21/2023 at 8:05 a.m. the FA indicated Mircera was given every 2 or 4 weeks. The information was based on the Mircera protocol and was unsure why it does not specify a frequency on the Kardex.</p> <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>Administrator will audit 100% of physician treatment orders for patients receiving Mircera to verify documentation of the frequency for administration of Mircera in accordance with the facility Micera protocol. The Facility Administrator or designee will review the results of the audits with teammates during homeroom meetings and with the Medical Director during monthly Quality Assurance and Performance Improvement meetings known as Facility Health Meetings, with supporting documentation included in the meeting minutes. The Facility Administrator is responsible for compliance with this plan of correction.</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152689	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 02/21/2023
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NAME OF PROVIDER OR SUPPLIER TERRE HAUTE DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP COD 504 6TH STREET TERRE HAUTE, IN 47807
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	<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> <ul style="list-style-type: none"> (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>(2) The policies and procedures of this section do not apply to the following facility staff:</p> <ul style="list-style-type: none"> (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. <p>(3) The policies and procedures must include, at a minimum, the following components:</p> <ul style="list-style-type: none"> (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 			

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	<p>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 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</p>			

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	<p>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 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</p> <p>(x) Contingency plans for staff who are not fully vaccinated for COVID-19.</p> <p>Effective 60 Days After Publication:</p> <p>(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 facility failed to ensure all visitors were screened daily Covid-19 for 1 of 2 survey days.</p> <p>Findings include:</p>	V 0800	100% of clinical teammates will be 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	03/15/2023

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NAME OF PROVIDER OR SUPPLIER TERRE HAUTE DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP COD 504 6TH STREET TERRE HAUTE, IN 47807		
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	<p>A 07/19/2021 Covid-19 Facility Lobby Guidance was provided by the FA (Facility Administrator) on 2/21/2023 at 8:10 a.m. The guidance indicated, but was not limited to, "Conduct an Entrance Evaluation at the entrance to the facility (and Advanced Screening, if indicated, in a dedicated room) in a timely manner."</p> <p>On 2/20/2023 at 9:30 a.m. facility staff failed to screen the surveyor for Covid-19 (virus) signs and symptoms prior to entering the treatment area.</p> <p>During an interview on 2/20/2023 at 4:00 p.m. the FA agreed all visitors should be screened for Covid-19.</p>		<p>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, 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-22-09ALL 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</p>		

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			<p>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 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</p>	

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			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 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).	