

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

PRINTED: 03/07/2023
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152624	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 02/15/2023
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE TREE CITY	STREET ADDRESS, CITY, STATE, ZIP COD 999 N MICHIGAN AVE GREENSBURG, IN 47240
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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: February 13th, 14th, and 15th of 2023 Census: In-Center Hemodialysis 21 Peritoneal Dialysis 3 At this Emergency Preparedness Survey, Fresenius Medical Care Tree City, was found in compliance with Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers, 42 CFR 494.62. QR Completed 2/21/2023 A4	E 0000		
V 0000 Bldg. 00	This visit was for a Federal Core ESRD Recertification Survey. Survey Dates: February 13th, 14th, and 15th of 2023 Census: In-Center Hemodialysis 21 Peritoneal Dialysis 3	V 0000		
V 0228 Bldg. 00	494.40(a) MIXING SYSTEMS-LABELING 5.4.4.1 Mixing systems: labeling Labeling strategies should permit positive identification by anyone using the contents of			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Dawn	Nelson	03/03/2023

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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	<p>mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine.</p> <p>Mixing tanks: Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling should remain on the mixing tank until the tank has been emptied.</p> <p>Bulk storage/dispensing tanks: These tanks should be permanently labeled to identify the chemical composition or formulation of their contents.</p> <p>Concentrate jugs: At a minimum, concentrate jugs should be labeled with sufficient information to differentiate the contents from other concentrate formulations used at the facility.</p> <p>Based on record review, observation, and interview, the facility failed to ensure the labeling of the bicarbonate mixing system for proper identification was in place in 1 of 1 facility observed.</p> <p>Findings Include:</p> <p>A policy titled, "Concentrate Labelling Requirements," dated 5/27/2021, Version 5, was provided by the administrator on 2/25/2023 at 4:50 p.m. The policy indicated, but was not limited to, "Policy Temporary Labeling (Incenter, Inpatient)" ... "When a mix tank contains a solution, a label identifying the solution must be conspicuously displayed on the tank and must remain until the mix tank is emptied. Mix tank labeling must</p>	V 0228	<p>V228 Mixing systems-labeling. On 02/24/2023, the Clinic Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on Policies titled Concentrate Labeling Requirements. Emphasis will be placed on The requirement that all storage tanks for concentrates must be labeled and include, Contents identification. For example, "Bicarb", "Acid", "RO Water" or "Disinfectant" Chemical composition or formulation of concentrate</p>	03/10/2023

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	<p>include: Contents identification. For example, "Bicarb", "Acid", "RO Water" or Disinfectant. Chemical composition or formulation of concentrate. Concentrate family with appropriate symbol. Example: 45x. Catalog number of product. Date and time of mixing".</p> <p>During an observation of the water room on 2/15/2023 at 1:18 p.m. the bicarbonate mixing tank was observed with clear fluid present approximately 1/3 full. No temporary labeling that included the content identification or when it was mixed was observed.</p> <p>During an interview on 2/25/2023 at 1:18 p.m., the administrator indicated they could not advise when the bicarbonate present in the tank was initially mixed and a that agreed it was not properly labeled.</p> <p>During an interview with on 2/25/2023 at 1:20 p.m., PCT A indicated the bicarbonate was prepared that morning and forgot to include the proper temporary labeling.</p>		<p>Concentrate family with appropriate symbol. Example: 45x⁻² Catalog number of product Date and time of mixing Effective 02/27/23, the Clinic Manager or designee will conduct daily audits, utilizing the Water Room Audit Tool, for 2 weeks. Once compliance is sustained at 100%, the Governing Body will resume regularly scheduled audits based on the QAI calendar. Monitoring will be done monthly through the Clinic Audit Checklist with any non-compliance noted in the monthly meeting. minutes. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinic Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate.</p>	

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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		The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The in-service sheets are available in the clinic for review. Concentrate Labeling Requirements Completion Date: 3/10/23	

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	<p>arrangement.</p> <p>(2) The policies and procedures of this section do not apply to the following facility 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)</p>			
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	<p>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 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</p>			

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	<p>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: (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;</p> <p>Based on record review, observation, and interview, the facility failed to ensure the possible spread of the COVID-19 by unvaccinated staff members to patients and other staff members by failing to have additional precautions in 1 of 1 facilities observed.</p> <p>Findings Include:</p> <p>A policy titled, "Vaccination Requirements for Staff of CMS-Certified Facilities," dated 11/7/2022 Version 6 was provided by the Director of Operations on 2/15/2023 at 5:04 p.m. The policy indicated, but was not limited to, "It is reasonable to expect Fully Vaccinated staff members will remove the face mask when in the breakroom to have a beverage, food, or other personal breaks.</p>	V 0800	<p>FRESENIUS MEDICAL CARE TREE CITY DIALYSIS Plan of Correction for Recertification Provider Identification Number: 15-2624 Date of Survey: 2/15/23 V800 COVID-19 Vaccination of Facility Staff On 02/24/2023, the Clinic Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on COVID-19 Vaccination Requirements for Staff of CMS-Certified Facilites Guidance on Dialyzing and Infection Control Practices During a COVID-19 Endemic in Fresenius Kidney</p>	03/10/2023

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	<p>Unvaccinated staff may briefly remove the face mask when in the breakroom to have a beverage or snack while maintaining a minimum distance of 6-feet from all other staff. Unvaccinated staff must don face mask immediately after eating/drinking. It is strongly recommended that unvaccinated staff only remove the face mask in the breakroom or other areas of the facility when no other staff are present."</p> <p>A policy titled, "Guidance on Dialyzing and Infection Control Practices During a COVID-19 Endemic in Fresenius Kidney Care (FKC) Dialysis Clinics," dated 11/7/2022 Version 3 was provided by the administrator on 2/25/2023 at 12:40 p.m. The policy indicated but was not limited to, "Staff must practice social distancing (separated by at least 6 ft) in breakrooms and other areas of the clinic to avoid the potential of spreading infection among unmasked staff members while breaking to snack or eat meals." ... "It is reasonable to expect fully vaccinated staff members will remove the face mask when in the breakroom to have a beverage, food or other personal breaks.</p> <p>Unvaccinated staff may briefly remove the face mask while in the breakroom to have a beverage or snack while maintaining a minimum of 6 feet from all other staff. Unvaccinated staff must don face mask immediately after eating/drinking. It is strongly recommended that unvaccinated staff only remove the face mask in the breakrooms or other areas of the facility when no other staff are present."</p> <p>An untitled, undated document was provided by the administrator on 2/13/2023 at 4:07 p.m. The document entailed a list of employee's vaccination status. The document indicated that PCT A (Patient Care Technician) had an approved Religious Exemption as of 11/15/2021. All other</p>		<p>Care (FKC) Dialysis Clinics Emphasis was placed on: Covered employees who are Exempt from Vaccination must follow the Company's current policies on Coronavirus disease screening, infection control and protective personal equipment. All employees must be screened for ongoing signs and symptoms of COVID-19 disease. Screening of all employees will be conducted at the start of each work shift. At a minimum, employees, depending upon their role, are required to wear the following PPE in all FKC facilities: Surgical mask or higher-grade respirator face mask (i.e., N95 respirator) at all times. Staff must practice social distancing (separated by at least 6 ft) in breakrooms and other areas of the clinic to avoid the potential of spreading infection among unmasked staff members while breaking to snack or eat meals. Employees must wear a face mask and practice social distancing (separated by 6 ft) in other common areas (e.g., breakrooms, conference rooms, restrooms). Unvaccinated staff may briefly remove the face mask while in the breakroom to have a beverage or snack while maintaining a minimum distance of 6 feet from all other staff. Unvaccinated staff must don face mask immediately after eating/drinking. Effective</p>	

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	<p>listed staff were vaccinated per CDC guidelines.</p> <p>An interview on 2/15/2023 at 10:30 a.m. was completed with the administrator. The administrator indicated she was unaware of additional precautions taken to mitigate the spread of COVID-19 with unvaccinated employees.</p> <p>An interview on 2/15/2023 at 12:04 p.m. was completed with PCT A. PCT A indicated that the facility attempts to stagger lunches to avoid more than 2 staff members in the breakroom at one time. If there are two employees in the breakroom, social distancing is observed, one individual at one end of the table while the second individual is at the opposite end of the table. Face masks are not worn during the breaks/lunches to eat/drink.</p> <p>An interview on 2/15/2023 at 4:15 p.m. with the Director of Operations was completed. The Director of Operations indicated that both vaccinated and unvaccinated staff members are required to wear a surgical or N95 mask in all patient care areas. While in the breakroom, unvaccinated staff must observe social distancing, but also agreed that all staff members are to abide by social distancing. Indicated that unvaccinated employees may only remove face mask to eat/drink and must replace mask immediately after eating/drinking while vaccinated employees can have mask off during duration of break/lunch.</p>		<p>03/04/2023, all exempt, unvaccinated employees will be provided a N95 respirator to use as a source control option in lieu of a surgical face mask at their discretion , a surgical face mask or N95 mask will be required at all times while present in the facility. Effective 03/06/2023, Clinical Manager or designee will conduct daily audits of the COVID-19 Screening Form with specific focus on ensuring patients and employees are screened for ongoing signs and symptoms of COVID-19 disease for 2 weeks. Effective (date), Clinical Manager or designee will also conduct visual audits daily with a focus on ensuring that unvaccinated staff only remove the face mask in the break room or other areas of the facility when no other staff are present utilizing the Clinic Audit Checklist for 2 weeks. Once compliance is sustained at 100%, the Governing Body will then resume regularly scheduled audits based on the QAI calendar. Any noncompliance will be documented in the QAI meeting minutes in eQUIP. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI</p>	

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			<p>Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. COVID-19 Vaccination Requirements for Staff of CMS-Certified Facilities Guidance on Dialyzing and Infection Control Practices During a COVID-19 Endemic in Fresenius Kidney Care (FKC) Dialysis Clinics External POC Report Page 3 of 3 Completion Date: 3/10/23</p>	