STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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	An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62. Survey Dates: July 11-13, 2022 Census: 41 in-center At this Emergency Preparedness survey, FMC Munster was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. QR Completed 7/26/2022 A4	E 0000		
V 0000 Bldg. 00	This visit was for a Federal complaint survey of an ESRD Provider. Survey Dates: July 11-13, 2022 Complaint: IN00253322 - Substantiated. Federal deficiencies were cited. Unrelated deficiencies were cited. Complaint: IN00253498 - Substantiated. Federal deficiencies were not cited. Unrelated deficiencies were cited. Complaint: IN00294682 - Substantiated. Federal deficiencies were not cited. Unrelated deficiencies were cited. Complaint: IN00342166 - Substantiated. Federal deficiencies were cited. Unrelated deficiencies	V 0000		

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

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	were cited. Census by Service Type: In-Center Hemodialysis: 41 Home Hemodialysis: N/A Home Peritoneal dialysis: N/A Total Census: 41			
V 0111 Bldg. 00	494.30 IC-SANITARY ENVIRONMENT 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. Based on observation, record review, and interview the facility failed to ensure the bandage/gauze on each needle site was clean and dry prior to discharge and failed to minimize the potential transmission of infectious agents from the ESRD (end stage renal disease) unit to other public areas in 1 of 1 discontinuation of dialysis care for an AV fistula or graft. (Patient 6) Findings include: 1. A 5/02/2022 policy titled Infection Control Overview was provided by the Administrator on 7/11/2022 at 2:00 p.m. The policy indicated, but was not limited to, "... frequent exposure to blood and body fluids, close proximity of patients and staff, and the immunocompromised status of patients, makes a dialysis clinic a high risk for spreading infections disease." 2. An August 2020 article titled Care of Needling Sites Post Hemodialysis for Fistulas & Grafts (Hemostasis) indicated, but was not limited to, "Hemostasis is best achieved by applying mild,	V 0111	On July 28 and July 29, 2022, the Clinic Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on Post Treatment Fistula Needle Removal Policy Emphasis will be placed on ensuring the bandage/gauze on each needle site is clean and dry prior to discharge to minimize the potential transmission of infectious agents from the ESRD (end stage renal disease) unit. It is recommended that the arterial needle be removed first. This may prevent penetration of the needle tip through the patient's skin when needles have been placed in the same direction or less than 1-2 inches apart and reduce potential for a contaminated needlestick. The	08/11/2022

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	direct pressure, using sterile gauze and a two-finger technique over the needle sites for at least 10 minutes". 3. During an observation on 7/11/2022 at 2:40 p.m. patient 6 was observed holding pressure to the top left access site with a gloved hand for 5 minutes. PCT 2 removed gauze dressing and Sureseal (pressure bandage) from left access site to check for hemostasis (stop bleeding) and reapplied the same Sureseal and gauze dressing, reinforced with additional tape. PCT 2 failed to apply a clean and dry bandage to patient 6's access site prior to leaving the station. PCT 2 assisted patient 6 to the clean sink located away from the station to wash patient 6's hands. At that time, patient 6 began bleeding through both dressings from the top left access site. 4. During an interview on 7/12/2022 at 11:55 a.m. the RNCM indicated Sureseal had additional padding built into the dressing to add pressure and some patients want it left on because it unlodges the clot and will start bleeding so staff re-enforces the dressing instead of applying a clean dressing.		following steps should be performed: · Fold gauze into approximately 1 x 1 inch size. · Stabilize the needle and carefully remove tape. This prevents tape from catching on skin or clothing as the needle is being removed. · Only remove tape from the needle being pulled. · Position the gauze over the insertion site without applying pressure. Pressure on the needle bevel is painful for the patient and may damage the vessel. · Place middle and index fingers on top of the gauze. Carefully remove the needle at approximately the same angle it was inserted, while applying pressure over the gauze. Removing the needle without changing the angle will prevent dragging the needle across the patient's skin. · Compress the needle exit site with two fingers. · Feel the pulse above and below the site of pressure. · If pulse is absent, release pressure on the access until the pulse is palpable to ensure blood flow through the access. Apply pressure continuously for 5-10 minutes before checking for hemostasis. · Once hemostasis is achieved: Remove the gauze. Apply antibiotic cream if ordered	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
			by physician. Place Band-Aid, adhesive dressing or gauze dressing secured with clean tape. Effective August 1, 2022, Clinic Manager or designee will conduct weekly audits utilizing Infection Control audit tool for 4 weeks with a focus on ensuring that patient gauze is changed after hemostasis is achieved and a Band-Aid or new gauze is applied. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist. 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 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 root cause	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
			analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. 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.	
V 0114 Bldg. 00	494.30(a)(1)(i) IC-SINKS AVAILABLE A sufficient number of sinks with warm water and soap should be available to facilitate hand washing. Based on observation and interview, the facility failed to ensure a dedicated clean hand washing sink was plumbed with hot water for 1 of 4 sink observations. Findings include: 1. A 5/02/2022 policy titled Infection Control Overview was provided by the Administrator on 7/11/2022 at 2:00 p.m. The policy indicated, but was not limited to, "... frequent exposure to blood and body fluids, close proximity of patients and staff, and the immunocompromised status of patients, makes a dialysis clinic a high risk for spreading infections disease." 2. A 7/23/2019 job description titled Biomedical Technician II was provided by the Administrator	V 0114	On July 28 and July 29, 2022, the Clinic Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on Infection Control Policy Clinic Audit Checklist Emphasis will be placed on ensuring the clinic will dedicate a clean hand washing sink that is plumbed with warm water accessible within 15 secs (temp 105-120 degrees) for washing hands. The nature of dialysis, with frequent exposure to blood and body fluids, proximity of patients and staff, and the immunocompromised status of	08/11/2022

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	on 7/11/2022 at 2:00 p.m. The job description indicated, but was not limited to "... Performs scheduled and unscheduled semi-routine repair, maintenance activities and operational condition of all medical equipment, water systems and the physical plant in assigned facilities that ensure patient safety ... Collaborates with facility staff ..." 3. A review of the monthly Clinical Practice Checklist was provided by the Administrator on 7/13/2022 at 11:15 a.m. The checklist indicated, but was not limited to, "... handwashing sink(s) should be clean with hot and cold water present ..." 4. During an observation on 7/13/2022 at 9:50 a.m. the designated clean sink for hand washing between pod 2 and pod 3 was checked for hot water. The motion detected sink was activated and ran for 1 minute and 10 seconds. PCT 6 confirmed the water coming from the sink was cool to touch. At that time, the Bio/Med technician confirmed the water was cool and adjusted the valve below the sink. 5. During an interview on 7/13/2022 at 9:55 a.m. the Administrator indicated checking the designated sinks in the treatment area are not part of the facility environmental clinical audit. At 11:00 a.m. the Administrator indicated regulatory personnel was unable to find a specific policy on water temperature. At 11:20 a.m. the Administrator indicated the Bio/Med technician did not check the sinks for water temperature, but if staff knew the water was not hot they should report it.		dialysis patients, makes a dialysis clinic a high risk for spreading infectious disease. Effective August 1,2022, Clinic Manager or designee will conduct weekly audits utilizing Clinic Audit checklist for 4 weeks with a focus on ensuring that the hand washing sink will have accessible warm water within established time frame for washing hands. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist. 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 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 root cause	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
			analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. 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.	
V 0117 Bldg. 00	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS 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. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	used to deliver medications to individual patients, they must be cleaned between patients. Based on observation, record review, and interview, the facility failed to ensure precautions were in place to prevent the potential for cross contamination between a designated clean and dirty sink for 1 of 4 sink observations. Findings include: A 7/23/2019 job description titled Biomedical Technician II was provided by the Administrator on 7/11/2022 at 2:00 p.m. The job description indicated, but was not limited to "... Performs scheduled and unscheduled semi-routine repair, maintenance activities and operational condition of all medical equipment, water systems and the physical plant in assigned facilities that ensure patient safety ... Collaborates with facility staff ..." During an observation in the treatment area on 7/13/2022 at 9:55 a.m. one designated clean sink used for hand washing and one designated dirty sink were located approximately eight inches apart side by side one another with no splash guard to prevent cross contamination of blood or body fluids or used supplies. During an interview on 7/13/2022 at 9:55 a.m. the Bio/Med technician agreed there should be a splash guard between the two sinks.	V 0117	On July 28 and July 29, 2022, the Clinic Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on Infection Control Policy Dialysis Precautions Emphasis will be placed on ensuring precautions are in place to prevent the potential for cross contamination between a designated clean and dirty sink. Approach all supplies, and equipment used for a patient's treatment as if they are contaminated. Clean area: An area designated for clean and unused equipment, supplies and medications. Dirty area: An area where this is a potential for contamination with blood or body fluids and areas where contaminated or used supplies, equipment, blood supplies or biohazard containers are stored or handled; Clean areas should be clearly designated for the preparation and handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from dirty areas where used supplies, equipment or blood samples are handled or stored. Effective August 1,2022, Clinic Manager or designee will conduct	08/11/2022

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
			weekly audits utilizing Infection Control Audit tool for 4 weeks with a focus on ensuring that precautions will be in place for the designated handwashing sink and dirty sink to prevent cross contamination. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist. 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 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 root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
			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.	
V 0122 Bldg. 00	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, record review, and interview, the facility failed to ensure all surfaces of the treatment chair were disinfected and counter tops directly behind the treatment chairs were wiped wet with disinfectant once the patient left the station for 3 of 3 cleaning and disinfection of the dialysis station observations. (PCTs 2, 5, & 6) (Stations 5, 11, 16) Findings include: 1. A 11/04/2019 policy titled Cleaning and Disinfection of the Dialysis Station Procedure was provided by the CMRN on 7/13/2022 at 8:20 a.m. The policy indicated, but was not limited to, "Procedure ... disinfect the dialysis station after	V 0122	On July 28 and July 29,2022, the Clinic Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on Cleaning and Disinfection of the Dialysis Station Emphasis will be placed on ensuring areas including the dialysis machine, chair/bed and other reusable equipment or supplies utilized during dialysis treatment, patient training, and/or patient clinic visits. Equipment in the dialysis station may include	08/11/2022

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	each dialysis treatment: ... 3. Use a cloth wetted with 1:100 bleach solution or EPA-approved disinfectant to clean and disinfect the dialysis station (chairs ... etc.). Place the chair in Trendelenburg [chair fully reclined] position and open side panels if chair has swing open sides so all surfaces of the chair are accessible. 4. Clean all surfaces. Make the surfaces glisteningly wet and allow to air dry ... 5. Give special attention to the cleaning ... other surfaces that are frequently touched and potentially contaminated with patient's blood ... 7. ... area/wall around the wall box at the end of each treatment day ... ." 2. During an observation on 7/11/2022 at 10:45 a.m. PCT (patient care technician) 2 failed to ensure the counter tops directly behind the dialysis chair were wiped wet with disinfectant once the patient left station 5. 3. During an observation on 7/11/2022 at 10:50 a.m. PCT 6 failed to ensure the counter tops directly behind the dialysis chair were wiped wet with disinfectant once the patient left station 11. 4. During an observation on 7/11/2022 at 10:55 a.m. PCT 5 failed to ensure the right outside panel of the dialysis chair was wiped wet with disinfectant and failed to ensure the counter tops directly behind the dialysis chair were wiped wet with disinfectant once the patient left station 16. 5. During an interview on 7/12/2022 at 1:55 p.m. the Administrator indicated all panels of the treatment chair are to be disinfected. The Administrator indicated the cleaning personnel wipe down the counter tops at the end of the day.		(but is not limited to) the following: Dialysis machine/cycler and attachments such as IV pole, BP cuff and hand sanitizer/holder, organizer Chair/bed. The dialysis station could become contaminated with blood and other body fluids during treatment. After use, any non-disposable equipment and supplies brought into the dialysis station (ex. stethoscope) must be disinfected with 1:100 bleach or EPA registered disinfectant before being removed from the dialysis station. Effective August 1,2022, Clinic Manager or designee will conduct weekly audits utilizing the Infection Control Audit tool for 4 weeks with a focus on ensuring that all surfaces of the treatment chair and counter tops behind the chair are disinfected is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist. 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 Committee monthly.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
			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 root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. 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.	
V 0184 Bldg. 00	494.40(a) ENVIRONMENT-SECURE & RESTRICTED 8 Environment: secure & restricted The water purification and storage system should be located in a secure area that is readily accessible to authorized users. The location should be chosen with a view to minimizing the length and complexity of the distribution system. Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system.			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	Based on observation, record review, and interview, the facility failed to ensure the entrance that led to the water purification and storage system was secured from unauthorized persons for 1 of 1 facility observations. Findings include: A 12/18/2013 policy titled Physical Security and Facility Access was provided by the Administrator on 7/12/2022 at 1:15 p.m. The policy indicated, but was not limited to, "To ensure a secure and safe environment for all staff, visitors, and patients while on FKC [Fresenius Kidney Care] properties. ... Doors from the waiting area to the treatment area should remain closed and locked at all times while still allowing emergency access/exit. ... Restricted access must be maintained to prevent unwanted tampering with the water treatment equipment ... Locking all doors that allow access to the water treatment equipment. No exterior building door will be left unlocked unless under the continual supervision of a facility staff member." On 7/11/2022 at 8:30 a.m. the outside entrance door was unlocked. Upon entrance into the facility, no staff were attending the front office desk. Observed the patient lobby area and found an unlocked key-padded door leading to the water purification system, storage/supply area, and employee locker / lounge area. No staff were seen in the hallway leading to the water room or in the immediate vicinity. The facility failed to ensure the door leading to the water treatment area was locked and secured. During an interview on 7/11/2022 at 1:30 p.m. the RNCM was unaware the door from the patient lobby area to the water room was unlocked and	V 0184	On July 28 and July 29,2022, the Clinic Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on Physical Security and Facility Access Emphasis will be placed on ensuring the entrance that leads to the water purification and storage system is secured from unauthorized persons. All secondary external entrances (employee entrance doors, delivery doors) to the facility are to be kept closed and locked when not in use while still allowing emergency access. No persons other than authorized personnel are to be admitted to the facility through secondary entrances. All supply storage rooms are to be limited to authorized persons only unless egress through the area is necessary for emergency evacuation of the facility. Restricted access must be maintained to prevent unwanted tampering with the water treatment equipment. The facility must be maintained to prevent unwanted entry by outside persons not involved in the daily operation of the clinic. This is accomplished by: Locking all doors that allow access to the water treatment equipment. Effective August 1,2022, Clinic Manager or designee will conduct	08/11/2022

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	unattended. RNCM indicated the cleaning staff must have left the door unlocked. During an interview on 7/12/2022 at 10:00 a.m. the Administrator and RNCM indicated the door's pad lock was broken and the cleaning crew did not report it to anyone at the facility. The Administrator did not indicate the facility routinely checks the locks to ensure none are broken. At that time, the Bio/Med tech indicated the latch to the keypad door was stuck leaving the door closed but not secured.		weekly audits utilizing the Clinic Audit Checklist tool for 4 weeks with a focus on ensuring that all entrances that lead to the water purification area is secure and is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist. 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 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 root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible to provide oversight to ensure the	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
			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.	
V 0544 Bldg. 00	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. Based on record review and interview, the facility failed to ensure a licensed nurse obtained a clarification order for the DFR (dialysis flow rate) for 1 of 5 records reviewed. (Patient 3) Findings include: 1. A 9/29/2028 policy titled Patient Assessment and Monitoring was provided by the Administrator on 7/11/2022 at 2:00 p.m. The policy indicated, but was not limited to, "Check dialysis flow rate setting is correct, and the prescribed flow is being delivered." 2. The clinical record for patient 3 was reviewed on 7/11/2022. Patient 3's Patient Transfer record indicated physician orders dated 6/20/2022 for DFR 500 mL/min (milliliters/minute). 3. A record review for patient 3 indicated a prescribed DFR of 500 mL/min. The treatment records for the following dates indicated the DFR	V 0544	On July 28 and July 29, 2022, the Clinic Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on Patient Assessment and Monitoring Emphasis will be placed on ensuring the licensed nurse obtained a clarification order for the DFR (dialysis flow rate). Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. Check machine settings and measurements; check dialysate flow rate setting is correct, and the prescribed flow is being delivered. Document any findings and interventions in the	08/11/2022

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	ran at 800 mL/min: 7/6/2022 initiated by PCT 3; 7/1/2022 initiated by PCT 3; 6/29/2022 initiated by PCT 6; 6/27/2022 initiated by PCT 2, 6/22/2022 initiated by RN 3; and 6/13/2022 initiated by PCT 1. No documentation within the treatment notes indicating why the DFR did not run at the physician ordered prescription rate. 4. During an interview on 7/12/2022 at 2:00 p.m. the Administrator indicated there was a nationwide shortage of GranuFlo® Dry Acid Concentrate and that was why the DFR was set at 800 instead of 500 for patient 2. The Administrator agreed the ordered prescription should match what was given during dialysis treatment and a clarification order should have been obtained.		medical record and notify physician if order change is necessary. Effective August 1,2022 Clinic Manager or designee will conduct weekly audits on 10% of treatment sheets utilizing the Medical Record Audit tool for 4 weeks with a focus on ensuring the correct DFR is obtained, or documentation is present why ordered rate is not and is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist. 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 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	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
			findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. 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.	
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;			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	spread of COVID-19, for all staff who are not fully vaccinated for COVID-19; (iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (b)(1) of this section; (v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC; (vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law; (vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements; (viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains: (A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and (B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	COVID-19 vaccination requirements for staff based on the recognized clinical contraindications; (ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and (x) Contingency plans for staff who are not fully vaccinated for COVID-19. Effective 60 Days After Publication: (ii) A process for ensuring that all staff specified in paragraph (b)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations; Based on observation, record review, and interview, the facility failed to ensure additional precautions were implemented to mitigate the spread of COVID-19 (coronavirus) for unvaccinated staff that provided direct patient care for 2 of 3 in-center treatment observation days, which had the potential to affect all in-center patients. (PCT's 1 & 4) Findings include: 1. A 4/20/2022 policy titled COVID-19 Vaccination Requirement for Staff of CMS-Certified Facilities	V 0800	On July 28 and July 29,2022, the Clinic Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on Guidance on Dialyzing and Infection Control Practices During a COVID-19 Endemic in Fresenius Kidney Care Dialysis Clinics COVID-19 Vaccination Requirements for Staff of	08/11/2022

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	(Ref. # 62106) was provided by the Administrator on 7/12/2022 at 11:30 a.m. The policy indicated, but was not limited to, "FMC Employees Exempt from Vaccination ... Covered employees who are Exempt from Vaccination must follow the Company's current policies on Coronavirus disease screening, infection control and protective personal equipment." 2. A 5/02/2022 policy titled Infection Control Overview was provided by the Administrator on 7/11/2022 at 2:00 p.m. The policy indicated, but was not limited to, "... frequent exposure to blood and body fluids, close proximity of patients and staff, and the immunocompromised status of patients, makes a dialysis clinic a high risk for spreading infections disease." 3. Review of the facility Covid vaccination exemptions on 7/12/2022 indicated PCT 1 and PCT 4 were exempt. 4. During an observation of direct patient care on 7/12/2022, between 8:30 a.m. to 12:00 p.m. Patient Care Technician (PCT) 1 was observed wearing a surgical (loose fitting) mask while in the treatment area during dialysis. The facility failed to ensure additional precautions were developed and implemented for unvaccinated staff while providing direct patient care in the treatment area. 5. During an interview on 7/12/2022 at 8:20 a.m. PCT 1 indicated he/she only wears a N95/K95 (close facial fitting mask that filters airborne particles) when providing direct patient care for a Covid positive patient. PCT 1 indicated he/she was not required to wear a fitted N95 mask while in the treatment area, nor was offered one to wear due to being exempt from the Covid vaccination. PCT 1 indicated he/she does not perform a weekly		CMS-Certified Facilities Personal Protective Equipment Emphasis will be placed on preventing the transmission of Coronavirus Disease (COVID-19-virus) and provide guidance on infection control and vaccination requirements as required by Centers for Medicaid and Medicare Services (CMS). It is the responsibility of All direct and indirect staff of CMS-certified facilities (Covered Staff), including Clinical Manager, Charge Nurse or Team Leader, direct patient care staff (including physicians and physician extenders), and other indirect patient care staff, service providers, and certain non-clinic staff who interact with Covered Staff, are required to adhere to the guidance outlined in this policy. Additional emphasis was placed on Fresenius Medical Care (FMC) employees may be approved for exemption from the vaccination requirements after submitting one of the exemptions request forms referenced below. The following are the possible bases of exemption, subject to the specific criteria set out in the applicable forms: Medical and Religious Exemption. Covered employees who are Exempt from Vaccination must follow the Company’s current policies on Coronavirus disease	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
	Covid test. PCT 1 indicated he/she performs hand hygiene, social distances, self-screen for Covid, and cleans/disinfects areas in the treatment room. 6. During an observation of direct patient care on 7/13/2022 between 8:00 a.m. to 11:00 a.m. PCT 4 was observed wearing a surgical (loose fitting) mask while in the treatment area during dialysis. The facility failed to ensure additional precautions were developed and implemented for unvaccinated staff while providing direct patient care in the treatment area. 7. Review of the Governing Body meeting minutes dated June 2, 2022, indicated the dated 4/20/2022 policy titled COVID-19 Vaccination Requirement for Staff of CMS-Certified Facilities (Ref. # 62106) was not reviewed. 8. During an interview on 7/12/2022 at 1:55 p.m. Facility Administrator (FA), indicated the Indiana facilities follow FMC facility policy which does not require additional precautions for unvaccinated staff while providing direct patient care.		screening, infection control and protective personal equipment. Effective August 1,2022 the Clinic Manager or designee will conduct infection control audits daily for two weeks, then weekly for one month utilizing the Infection Control Audit Tool. The focus will be on employee COVID-19 screening and Personal Protective Equipment (PPE) usage per policy. Once compliance is sustained at 100%, the Governing Body will resume regularly scheduled audits based on the QAPI calendar. Monitoring will be done through the Staff aggregate Report. 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 Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	07/13/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
			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 root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. 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.	