STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152550	A. BUILDING 00 B. WING	04/29/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE DEKALB COUNTY DIALYSIS	1144 W 15TH ST AUBURN, IN 46706

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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: April 27, 28, and 29, 2022 Census: 56 During this Emergency Preparedness survey, Fresenius Medical Care Dekalb Dialysis was found to be in compliance with the Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, including staffing and the implementation of staffing during a pandemic, at 42 CFR 494.62. QA: Area 2 Supervisor on May 10, 2022	E 0000		
V 0000 Bldg. 00	This visit was for a CORE Federal recertification survey of an ESRD provider. Survey Dates: April 27, 28, and 29, 2022 Census by Service Type: In Center Hemodialysis: 47 Home Hemodialysis: 2 Home Peritoneal dialysis: 7 Total Patients all Modalities: 56 Isolation Room / Waiver: 0 QA: Area 2 Supervisor on May 10, 2022	V 0000		
V 0113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE			

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

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Bldg. 00	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. Based on observation, record review, and interview, the facility failed to ensure all staff followed infection control practices specific to hand hygiene and glove changes when entering and leaving patient stations for 1 of 8 staff observed providing direct patient care (Patient Care Technician #3). Findings include: 1. A facility policy #47664, titled "Hand Hygiene" and dated 11/4/19, indicated but was not limited to " ... Hands will be decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water ... when ... before and after direct contact with patients. Entering and leaving the treatment area ... Immediately after removing gloves ...." 2. A facility policy #47665, titled "Hand Hygiene Procedure" and dated 9/26/18, indicated but was not limited to " ... Procedure for Decontaminating Hands with Alcohol Based Hand rubs ... Step 1. If gloves are worn, remove and discard in appropriate waste container ...." 3. During a treatment floor observation completed on 4/28/22 between 10:00 AM - 11:20 AM, Patient Care Technician (PCT) #3 was observed at 10:37 AM going directly from Station #4 to Station #3 (patients were present in both stations). The PCT changed gloves in between stations but failed to perform hand hygiene with the glove change. 4. At 10:52 AM, PCT #3 was observed entering	V 0113	On or before May 27, 2022, the Clinic Manager will hold a staff meeting and reinforce the expectations and responsibilities of the facility staff on policies: · Hand Hygiene Education emphasis was placed on: · Removal of soiled gloves and performing hand hygiene after direct contact with patient access and/or after contact with inanimate objects within the hemodialysis station. · Hand hygiene may be performed by hand washing or using an alcohol based hand rub. · Hand washing will include wetting hands, applying soap, rubbing hands vigorously, rinsing hands under running water and drying thoroughly with a disposable towel. Duration of the entire hand washing procedure will be 40-60 seconds. · Decontaminating hands with an alcohol based hand rub includes applying hand rub, rub hands together covering all surfaces of hands and fingers, allow to dry. Duration of the entire hand rub decontaminating procedure will be 20 seconds. Effective May 28, 2022, the Clinic Manager or designee will conduct	05/29/2022

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	Station #4 from the nurse's station and donned gloves. The PCT failed to perform hand hygiene prior to donning gloves. 5. At 10:55 AM, PCT #3 was observed initiating dialysis with an arteriovascular (AV) fistula for Patient #4. During the observation, the PCT was observed documenting on the dialysis machine's computer with a glove on one hand then donned a glove on the other hand after they had completed charting. The patient requested an arm cushion, PCT #3 removed a glove from one hand, obtained the arm cushion with the ungloved hand from a supply station outside of the patient station, returned to the patient station, and donned a new glove. Later during the observation, PCT #3 left the station, removed one glove, obtained an antiseptic wipe with the ungloved hand from the supply cart, reentered the station and donned a new glove. 6. An interview was conducted on 4/29/22 at 12:22 PM with the Administrator who confirmed staff should change gloves in between treatment stations, staff should perform hand hygiene and don gloves prior to entering a patient station, and staff should remove gloves and perform hand hygiene when going from a patient station to the (non-mobile) supply cart located outside of patient stations.		infection control audits daily for four weeks, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on practicing glove changes and hand hygiene per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAPI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAPI 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 QAPI 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 QAPI 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.	

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			Documentation of education, monitoring, QAPI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: May 29, 2022	
V 0128 Bldg. 00	494.30(a)(1)(i) IC-HBV-ISOLATION (EXISTING FACILITY) Isolation of HBV+ Patients To isolate HBsAg positive patients, designate a separate room for their treatment. For existing units in which a separate room is not possible, HBsAg positive patients should be separated from HBsAg susceptible patients in an area removed from the mainstream of activity. Based on observation, record review and interview, the facility failed to provide an isolation room, nor had a valid waiver, for the treatment of Hepatitis B positive patients, with the potential to affect all facility patients. Findings include: 1. During a flash tour on 04/27/22 at 11:00AM, observed 12 dialysis stations and no isolation room. 2. A facility policy, dated 03/20/13, and titled "Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+)" [liver infection caused by the hepatitis B virus], indicated but was not limited to " ... units existing prior to 10/14/2008 which do not currently accept or treat HBsAg positive patients must have a transfer agreement with a local chronic facility which has capacity for isolation ...."	V 0128	On or before May 27, 2022, the Clinic Manager will hold a staff meeting and reinforce the expectations and responsibilities of the facility staff on policies, Condition for Coverage, and State Operations Manual: ·Dialyzing Patients with Positive Hepatitis B Antigen. ·Transfer Agreement: Hepatitis B Antigen Positive Patients. ·End Stage Renal Disease (ESRD) Conditions for Coverage (CfCs) ·State Operations Manual (SOM), Chapter 2, Ref: QSO 18-22-ESRD; 2281A Isolation Room Waiver Education emphasis was placed on:	05/29/2022

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	3. An agency document, dated 03/10/22, and titled "Subject: Waiver of Isolation Room Requirements" indicated CMS (Centers for Medicare and Medicaid Services) denied the facility's request for an isolation room waiver. 4. During an interview on 4/27/22 at 4:53 PM, the Administrator relayed the facility had a transfer agreement with a local dialysis clinic and was not aware the facility waiver was denied. 5. The survey's Entrance Conference was conducted on 4/27/22 at 10:00 AM with the Clinical Manager. During the Entrance Conference, the Clinical Manager confirmed the facility did not have an isolation room to treat Hepatitis B positve patients. The Clinical Manager confirmed the facility had an approved waiver for the isolation room from CMS.		·All patients who are Hepatitis B antigen positive (HBsAg+) must dialyze under isolation precautions. ·A new facility built after February 9, 2009 must have a separate isolation room unless the facility has obtained a waiver from CMS for this requirement. ·Any facility that existed prior to February 2009 which expands its physical capacity AFTER February 9, 2009 must include an isolation room or secure a waiver. ·Units existing prior to 10/14/2008 which do not currently accept or treat HBsAg+ patients must have a transfer agreement with a local chronic facility which has capacity for isolation. The SOM 2281A - Isolation Room Waiver (Rev. 1, XX-XX-18) indicates the following: ·The ESRD CfCs at §494.30(a)(1)(i) refer to the requirements for the treatment of hemodialysis patients who are positive for hepatitis B (HBV+). Every certified ESRD facility must have the **capacity** to treat one or more HBV+ patients in an isolation room or isolation area, or have an approved waiver under §494.30(a)(1)(ii). ·**Sufficient capacity** takes into account the availability of dialysis facilities with isolation rooms in the proximate geographic area. The proximate area must not create an undue hardship on the	

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			patient to have to relocate to the proximate facility. ESRD facilities certified prior to February 9, 2009 **MAY** have an isolation area, an isolation room or apply for an isolation room waiver to provide isolation services. In those instances where a patient already being served by the ESRD facility develops the need for isolation, the ESRD facility must have written arrangements in place to affect the safe transfer of the patient to another local ESRD facility which does provide isolation services. Dekalb received the initial CMS certification on 6/9/97. The clinic had a Hepatitis B Transfer Agreement in place upon surveyor arrival dated 6/13/2012. The Operations team understood the existing Hepatitis B Transfer Agreement to be sufficient to meet HBsAg+ patient needs during a seroconversion for existing patients and does not admit HBsAg+ patients directly. The Director of Operations applied for the Hepatitis B waiver per surveyor instructions. Effective May 28, 2022, the Clinic Manager or designee will conduct infection control audits daily for four weeks, then weekly for one month, then monthly utilizing the Infection Control Monitoring Tool. The focus will be on ensuring patients who are Hepatitis B antigen positive (HBsAg+) dialyze	

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			under isolation precautions. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAPI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAPI 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 QAPI 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 QAPI 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. Documentation of education, monitoring, QAPI, and Governing Body is available for review. The Facility Administrator is responsible for overall compliance. Completion Date: May 29, 2022	

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V 0504 Bldg. 00	494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs. Based on record review and interview, the facility failed to ensure the Patient Care Technician (PCT) notified the Registered Nurse (RN) on duty for a patient's blood pressure reading being out of normal parameters for 3 of 3 hemodialysis treatments reviewed for a patient with blood pressure out of parameters (#4). Findings include: 1. A facility policy titled "Patient Assessment and Monitoring," dated 9/29/18, indicated but was not limited to " ... Monitoring During Treatment ... Follow the steps below for monitoring patient and machine parameters during treatment: Step 1: Blood Pressure: Record blood pressure ... Report to the nurse: Systolic blood pressures [first number of blood pressure reading] greater than 180 mm/Hg [millimeters of mercury, measurement of blood pressure]. Diastolic blood pressure [second number of blood pressure reading] greater than 100 mm/Hg ...." 2. The clinical record of Patient #4 was reviewed on 4/29/22 and indicated a start of care date of 4/20/21 and indicated the primary cause of their kidney failure was high blood pressure. The record included a treatment sheet for the patient's in-center hemodialysis treatment completed on 4/27/22. The treatment sheet indicated PCT #1 documented Patient #4's blood pressure was	V 0504	On May 27, 2022, the Clinic Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Patient Assessment and Monitoring Education emphasis was placed on: · Patient Care Technicians (PCTs) are required to notify the Registered Nurse (RN) for SBP >180 mm/Hg or <100 mm/Hg and/or DBP >100 mm/Hg or <50 mm/Hg, · RN documentation in the electronic medical record of blood pressure (BP) out of parameters, assessment and intervention when indicated. · The interdisciplinary team will provide the necessary care and services to manage the patient's volume status. Effective May 28, 2022, the Clinical Manager or designee will conduct hemodialysis treatment sheet audits on a minimum of five patient records daily for two weeks, then weekly for four weeks utilizing the Patient Treatment	05/29/2022

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	192/108 at 11:30 AM (one minute into the start of treatment), 189/106 at 12:09 PM, 176/103 at 2:00 PM, 185/106 at 2:37 PM, and 182/107 at 3:02 PM. The treatment sheet indicated PCT #2 documented the patient's blood pressure was 197/113 at 12:36 PM and the patient's treatment ended at 3:30 PM. The record failed to evidence PCTs #1 and #2 notified the nurse of Patient #4's elevated blood pressure readings during treatment. a. The record included a treatment sheet for Patient #4's in-center hemodialysis treatment completed on 4/21/22. The treatment sheet indicated Patient #4's treatment began at 10:40 AM, PCT #2 documented the patient's blood pressure was 192/102 at 1:32 PM, PCT #3 documented the patient's blood pressure was 207/105 at 2:03 PM, and the patient's treatment ended at 2:35 PM. The record failed to evidence PCTs #2 and #3 notified the nurse of the patient's elevated blood pressure readings during treatment. b. The record included a treatment sheet for Patient #4's in-center hemodialysis treatment completed on 4/19/22. The treatment sheet indicated Patient #4's treatment began at 10:38 AM, PCT #5 documented the patient's blood pressure was 190/106 at 10:46 AM, 188/94 at 2:03 PM, and 185/92 at 2:35 PM. Patient #4's treatment ended at 2:40 PM. The record failed to evidence PCT #5 notified the nurse of the patient's elevated blood pressure readings during treatment. 3. An interview was conducted on 4/29/22 at 3:55 PM with the Administrator who confirmed the patient care technician should notify the nurse on duty of a patient's blood pressure outside of normal parameters and document the nurse was		Sheet Monitoring Tool. The focus will be on PCT notification to the RN for BP out of parameters per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAPI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAPI 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 QAPI 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 QAPI 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. Documentation of education, monitoring, QAPI, and Governing Body is available for review.	

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	notified.		The Clinic Manager is responsible for overall compliance. Completion Date: May 29, 2022	
V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on observation, record review, and interview, the Medical Director failed to ensure all policies and procedures were followed by staff for 4 of 5 observations of accessing an arteriovenous (AV) fistula (surgical joining of an artery and a vein for dialysis) site (Patients #3, 8, 12, 17) and 1 of 5 observations of post dialysis access care for an AV fistula (Patient #10). Findings include: 1. An agency policy #45178, titled "Access Assessment and Cannulation" and dated 11/1/21, indicated but was not limited to " ... Skin disinfection .... Step 4 Discard gloves and perform hand hygiene ... Needle Placement Procedure ... Step 1 Perform hand hygiene and don clean gloves ...." 2. During an observation on 4/27/22 at 1:30 PM at Station #3, Patient Care Technician (PCT) #1 accessed an arteriovenous fistula on Patient #3. After disinfection of the site, PCT #1 inserted the needle into the fistula without discarding gloves, completing hand hygiene, and putting on new gloves.	V 0715	On or before May 27, 2022, the Clinic Manager will hold a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies and Governing Body By-Laws: · Medical Director Roles and Responsibilities · Access Assessment and Cannulation Education emphasis was placed on: · Ensuring 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 non-physician providers. · The Medical Director is responsible for the delivery of patient care in the Facility. · Medical Director Responsibilities include, but are	05/29/2022

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	3. During an observation on 4/28/22 at 9:00 AM at Station #3, PCT #2 accessed an arteriovenous fistula on Patient #8. After disinfection of the site, PCT #2 inserted the needle into the fistula without discarding gloves, completing hand hygiene, and putting on new gloves. 4. During an observation on 4/28/2022 at 9:30 AM at Station #12, PCT #2 accessed an arteriovenous fistula on Patient #12. After disinfection of the site, PCT #2 inserted the needle into the fistula without discarding gloves, completing hand hygiene, and putting on new gloves. 5. During an observation on 4/29/2022 at 9:40 AM at Station #6, PCT #3 accessed an arteriovenous fistula on Patient #17. After disinfection of the site, Employee M inserted the needle into the fistula without discarding gloves, completing hand hygiene, and putting on new gloves. 6. An interview was conducted on 4/29/2022 at 3:50 PM with the Administator and Home Training Nurse #1. During the interview, the Administrator confirmed the facility's policy for AV fistula access and cannulation required hand hygiene between disinfection and accessing the AV fistula site.7. A facility document titled "Article IV [4] - Administration," revised 12/2/19, indicated but was not limited to "4.1 Medical Director ... 4.1.2 Duties: ... The Medical Director is responsible for the delivery of patietn care and outcomes in the Facility ... 4.1.3 Policies and Procedures ... the Medical Director must ... b. Ensure that all policies and procedures relative to ... patient care ... infection control ... are adhered to by all individuals who treat patients in the Facility ...." 8. During an observation on 4/28/2022 at 10:44		not limited to, the following: b. oversight of staff education, training, and performance. c. Review and approval with the policies and procedures. d. Oversight of all Medical Staff Members and their compliance with the Facility policies and procedures. · Ensure staff remove gloves after skin disinfection, perform hand hygiene, and don new gloves prior to hemodialysis needle into the arteriovenous fistula (AVF). Effective May 28, 2022, the Clinical Manager or designee will conduct infection control audits daily for four weeks, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on hand hygiene and access cannulation per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAPI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAPI 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 QAPI Committee monthly. The Director of Operations is responsible to present the status	

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	AM at station #5, Patient Care Technician (PCT) #1 was observed discontinuing Patient #10's dialysis treatment with an arteriovenous (AV) fistula. During the observation, PCT #1 failed to remove gloves, perform hand hygiene, and don new gloves immediately prior to removing the patient's fistula cannulation needles. 9. An interview was conducted on 4/29/22 at 12:22 PM with the Nurse Director and Administrator. During the interview, the Administrator confirmed when removing the cannulation needles from an AV fistula, staff should perform hand hygiene and change gloves immediately prior to removing the needles.		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 QAPI 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. Documentation of education, monitoring, QAPI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: May 29, 2022	
V 0765 Bldg. 00	494.180(e) GOV-INTERNAL GRIEVANCE SYS ID/IMPLEMENTED The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. The grievance process must include- (1) A clearly explained procedure for the submission of grievances. (2) Timeframes for reviewing the grievance. (3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance. Based on record review and interview, the agency	V 0765	On or before May 27, 2022, the	05/29/2022

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	failed to document the resolution and follow-up of grievances for 2 of 6 patient grievances (Patient #11 and 15). Findings include: 1. A facility policy, dated 04/04/14 and titled "Patient Grievance Procedure," indicated but was not limited to " ... CM [case manager] reports back to the patient when a resolution is attained ... when the grievance cannot be immediately resolved, the CM must provide the patient / representative with updates periodically ...." 2. Review of a binder serving as the agency grievance log revealed two grievances without resolutions. a. The binder contained a grievance, dated 06/25/21, from Patient #15 related to care, HIPPA, and infection control. The Administrator documented the patient grievance was not substantiated. The grievance log failed to evidence a resolution and follow up with patient #15. b. The binder contained a grievance, dated 08/25/21, from Patient #11 regarding care. The Administrator documented the patient grievance was not substantiated. The grievance log failed to evidence a resolution and follow up with patient #11. 3. An interview was conducted with the Administrator on 4/29/2022 at 11 AM. During the interview, the Administrator was not able to provide documentation to evidence the patients received information regarding the resolution of their grievances.		Clinic Manager will hold a meeting with the**/bInterdisciplinary Team (IDT), Medical Director and staff and reinforced the expectations and responsibilities of the facility staff on policy:** **·Patient Grievance Procedure** **·Quality Assessment and Performance Improvement (QAPI)** **Education emphasis was placed on:** **·Documentation of resolution and follow-up of patient grievances.** **·Case Manager will report back to the patient when a resolution is attained; when the grievance cannot be immediately resolved, the Case Manager must provide the patient and/or representative with updates periodically.** **·Complete documentation in the grievance log, including but not limited to resolution.** **·The QAPI process must include a review of patient grievances and record on the Grievance Log to include progress toward or complete resolution of a complaint.** **.** **To address the citation regarding the internal grievance process, the Clinic Manager will ensure that the Grievance Log is documented**	

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			accurately to include, but not limited to resolution. **To provide further oversight, the Director of Operations will review the QAPI minutes for accurate and complete documentation immediately after each months QAPI meeting to ensure patient grievances are documented accurately with resolution.** **The Medical Director will review the results of audits each month at the QAPI 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 QAPI 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 QAPI 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**	

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			effective and is providing resolution of the issues. Documentation of education, monitoring, QAPI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. C ompletion Date: May 29, 2022	
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 arrangement.			

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

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

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	vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and (x) Contingency plans for staff who are not fully vaccinated for COVID-19. Effective 60 Days After Publication: (ii) A process for ensuring that all staff specified in paragraph (b)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations; Based on record review and interview, the facility failed to develop and implement policies and procedures and a system of tracking to ensure staff whose COVID-19 vaccination was temporarily delayed or with an approved exemption for 2 of 2 employees with an approved temporary vaccination delay (Patient Care Technician #3 and 4). Findings include: 1. A facility policy #62106, titled "COVID-19 Vaccination Requirements for Staff of CMS-Certified Facilities" and dated 1/13/22, indicated but was not limited to " ... Definitions ... Covered staff includes all current staff as well as any new staff who provide any care, treatment, or other services in or for a CMS-certified facility and / or its patients ... Exempt from Vaccination means	V 0800	On May 27, 2022 the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the following: · Requirement COVID-19 Vaccination Requirements for Staff of CMS-Certified Facilities · COVID-19 Vaccination Aggregate Report: My Staff 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	05/29/2022

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	person who have been approved for an exemption from the applicable federal vaccine mandate, as described in this policy ... Policy : All Covered Staff must be Fully Vaccinated against COVID-19 ... Covered Staff who are Exempt from Vaccination must follow the Company's current policies on Coronavirus disease screening, infection control and protective personal equipment ...." 2. Centers for Disease Control and Prevention (4/21/22). "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States," retrieved 5/2/22, indicated but was not limited to " ... People who recently had SARS-CoV-2 infection may consider delaying their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic) ... COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma ...." 3. A log of facility employee COVID-19 vaccination status was reviewed on 4/28/22. The log indicated Patient Care Technician (PCT) #3 had an approved medical exemption effective 12/30/21 with an expiration date of 12/30/22. An agency document titled "Medical Exemption Request COVID-19 Vaccination 2021," completed for PCT #3 and dated 12/8/21, indicated the signing medical provider's recommendation for COVID-19 vaccination exemption was based on the employee receiving a monoclonal antibody infusion (date of infusion not indicated). The document also indicated the signing medical provider recommended the employee could receive the COVID-19 vaccine "3 months" from the date of infusion (specific date not indicated).		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 Exemption. All temporary delays in vaccination will require submission of request for medical exemption. Employees and their direct supervisor/manager will receive notification of the approval or denial of the requested exemption. Covered employees who are Exempt from Vaccination must follow the Company's current policies on Coronavirus disease screening, infection control and protective personal equipment.	

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	An interview was conducted with the Clinical Manager on 4/29/22 at 10:20 AM. During the interview, the Clinical Manager indicated PCT #3 received their monoclonal antibody infusion on 11/24/22. Three months from this date would be 2/24/22. An untitled document, indicated as an email exchange on 12/30/21 between a corporate human resources account and PCT #3 with the subject "About Case 1109213: COVID-19 Vaccine Medical Exemption: Approval," indicated the employee's request for medical exemption was approved and was valid until 3/8/22. A copy of a COVID-19 Vaccination Record Card for PCT #3 was reviewed on 4/29/22. The document indicated the employee received a two-dose series of the COVID-19 vaccine with their first dose on 3/8/22 and second dose on 4/5/22. 4. A log of facility employee COVID-19 vaccination status was reviewed on 4/28/22. The log indicated PCT #4 had an approved medical exemption, effective 11/17/21 with an expiration date of 11/17/22. An agency document titled "Medical Exemption Request COVID-19 Vaccination 2021" completed for PCT #4 and dated 11/15/21, indicated the signing medical provider's recommendation for COVID-19 vaccination exemption was based on the employee receiving a monoclonal antibody infusion for COVID-19 exposure on 10/11/21. The document also indicated the signing medical provider recommended the employee could receive the COVID-19 vaccine 90 days from the date of infusion (1/9/22).		Effective May 28, 2022, Clinic Manager or designee will conduct monthly audits of the status of employees with exemption status from COVID-19 vaccination to ensure all physician specific directions are followed utilizing the Staff Aggregate Report to ensure accurate dates are entered for follow up with staff member identified. Once compliance is sustained at 100 percent, the Governing Body will decrease frequency to then 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 QAPI 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 QAPI 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.	

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	An undated document, indicated as an email exchange between a corporate employee and PCT #4 with the subject "About Case 1087455: COVID-19 Vaccine Medical Exemption Request-National," indicated on 3/3/22 the corporate employee requested PCT #4 submit a new request for medical exemption, and the request was due by 4/2/22. The email exchange also indicated PCT #4 responded they were going to get the first dose of the vaccine on 3/24/22. A copy of a COVID-19 Vaccination Record Card for PCT #4 was reviewed on 4/29/22. The document indicated the employee received a two-dose series of the COVID-19 vaccine with their first dose on 3/24/22 and second dose on 4/14/22. 5. An interview was conducted on 4/29/22 at 12:22 with the Clinical Manager and Administrator. During the interview, the Administrator confirmed PCTs #3 and #4 had approved medical exemptions for the COVID-19 vaccine but the reasons for exemption were no longer valid after this regulation came into effect on 2/14/22, based on the CDC recommendations for delay in vaccination after monoclonal antibody infusion, therefore the employees were advised to either be vaccinated or request another exemption. The Administrator confirmed there was no facility policy which indicated the timeframe for vaccination after an exemption or temporary delay expired. The facility staff was unable to report how the dates of PCT #3's exemption expiration date of 3/4/22 and PCT #4's second medical exemption request date of 4/2/22 were chosen. The Administrator relayed that their corporate human resources was in charge of tracking all employee COVID-19 vaccination and exemption status.		The QAPI 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 in-service sheets are available in the clinic for review. Completion	

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