STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152611	A. BUILDING 00 B. WING	12/01/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE NEPHROLOGY MARSHALL COUN	2855 MILLER DR STE 209 PLYMOUTH, IN 46563

(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, for a Medicare participating End Stage Renal Disease Supplier. Date of survey: 11-29, 11-30 and 12-01-2021 Facility #: 006823 CCN: 152611 Stations: 16, there are no isolation rooms ICHD Patients: 61 Total Census: 61 At this Emergency Preparedness survey, Fresenius Medical Care Grant County, was found to have been in compliance with the requirements of Emergency Preparedness Requirements for Medicare participating providers and suppliers, including staffing and implementation of staffing during a Pandemic, at 42 CFR 494.62. Quality Review Completed on 12/6/21 by Area 3	E 0000		
V 0000 Bldg. 00	This visit was a CORE Recertification survey of an ESRD provider in conjunction with 1 complaint by the Indiana Department of Health.	V 0000		

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

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	Complaint: IN00317241: Substantiated. No related federal deficiencies were cited. Date of survey: 11-29, 11-30 and 12-01-2021 Facility #: 006823 CCN: 152611 Stations: 16, no isolation room ICHD Patients: 61 Total Census: 61 Quality Review Completed on 12/6/21 by Area 3			
V 0113 Bldg. 00	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. Based on observation, record review, and interview, the facility failed to demonstrate appropriate hand hygiene in 7 of 8 observations (Patient: #1, 6, 12, 13, interview #20) (Employee: C, E, and D) and 1 of 1 patient interview over 2 of 3 survey days. Findings include:	V 0113	On December 10, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy & procedure: · Hand Hygiene Education emphasis was placed on: · Change gloves and practice hand hygiene between each	12/30/2021

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	1. A September 2018 Fresenius Kidney Care policy dated 11-04-2019, titled, "Hand Hygiene" was provided by the Director of Operations (DOO), employee M on 12-01-2021 at 10:45 AM. The policy indicated but was not limited to, "Purpose: The purpose of this policy is to prevent transmission of pathogenic microorganisms to patients and staff through cross-contamination. Responsibility: All staff, patients ...Policy: Hand hygiene includes either washing hands with soap and water or using a waterless alcohol-based antiseptic hand rub with 60-90% alcohol content ...When ...Before and after direct contact with patients. Entering and leaving the treatment area. Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications ...Hand Hygiene: Patients: Patients should perform hand hygiene if able, prior to and after each dialysis treatment ..." 2. During an observation on 11-29-2021 at 1045 AM, the Licensed Practical Nurse (LPN), Employee C, was observed accessing the fistula (access site for dialysis) for patient #2 at station #11. Employee C completed the process and removed their gloves. Employee C did not perform hand hygiene. 3. During an observation on 11-29-2021 at 10:54 AM, the LPN, Employee C, was observed moving from station #11 to station #12. Employee C removed their gloves at station #11 without performing hand hygiene and applying new gloves. 4. During an observation on 11-29-2021 at 11:04 AM, the Patient Care Technician (PCT), Employee E, discontinued the treatment for patient # 1. Patient #1 was not instructed to perform hand hygiene after removing their glove when the		patient and station to prevent cross-contamination. · 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 December 13, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on changing gloves and practicing hand hygiene per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and	

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	pressure dressing was applied. 5. During an observation on 11-29-2021 at 12:05 PM, the PCT, Employee D, was observed removing their gloves while at station #14. They removed their gloves, applied new gloves, and did not perform hand hygiene. 6. On 12-01-2021 at 8:40 AM, the DOO, Employee M was queried about hand hygiene. When queried if patients should be offered the opportunity to wash their hands after removing their gloves and if the staff should perform hand hygiene before and after applying gloves, Employee M indicated they should. 7. During an observation on 11-29-2021 at 9:40 AM, patient #12 was observed holding pressure on their left arm fistula site (arterio-venous access for dialysis) post-dialysis with a gloved hand. The PCT, Employee N, applied a pressure bandage, and the patient removed their glove. The patient was not offered any hand sanitizer or instructed to perform hand hygiene before leaving the treatment floor. 8. During an observation on 11-29-2021 at 10:45 AM, patient #13 was observed holding pressure on their left arm fistula site post-dialysis with a gloved hand. The PCT, Employee F, applied a pressure bandage, and the patient removed their glove. The patient was not offered any hand sanitizer or instructed to perform hand hygiene prior to leaving the treatment floor. 9. During an observation on 11-30-2021 at 10:30 AM, patient #6 was observed holding pressure on their left arm fistula site post-dialysis with a gloved hand. The PCT, Employee Q, applied a pressure bandage, and the patient removed their glove. The patient was not offered any hand		Performance Improvement (QAI) calendar with oversight from the Governing Body. 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 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, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 30, 2021	

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	sanitizer or instructed to perform hand hygiene prior to leaving the treatment floor. 10. During an interview on 12-01-2021 at 8:45 AM, when discussing observations of the patients after post-dialysis holding pressure on their fistula sites and over access sites with gloved and process of hand hygiene after removing glove weighing on the treatment room-scale, the Clinical Manager (CM), Employee L, and Director of Operations (DOO), Employee M, confirmed the patients are to either wash hands or be offered hand sanitizer after the glove is removed post-dialysis prior to leaving the treatment center. 11. During a phone interview on 12-1-2021 at 9:45 AM, patient #20, was queried about staff offering hand sanitizer or hand hygiene after they remove their glove from their hand that held pressure on their access site. Patient #20 stated, "No Ma'am. They do not do that at this center."			
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 observations, record review, and interview, the facility failed to ensure the proper disinfection and cleaning of the dialysis stations in 5 of 5 observations over 1 of 3 survey days. (Employee: E, B, N, and F)	V 0122	On December 10, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Cleaning and Disinfection of	12/30/2021

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	Findings include: 1. On 12-01-2021 at 9:30 A.M., November 2020, Fresenius Kidney Care policy titled, " Cleaning and Disinfection of the Dialysis Station" was provided by the Director of Operations (DOO), employee M. The policy indicated but was not limited to, "...area including the dialysis machine, and other reusable equipment or supplies...all work surfaces shall be cleaned and disinfected...". 2. During an observation on 11-29-2021 at 10:45 AM, the Patient Care Technician (PCT), Employee E was cleaning station #14. The employee failed to clean the prime container inside and out after emptying the container. 3. During an observation on 11-29-2021 at 10:52 AM, the Registered Nurse (RN), Employee B, was cleaning station #10. The employee failed to clean the prime container inside and out after emptying the container. 4. During an observation on 11-29-2021 at 11:49 AM, the PCT, Employee E, was cleaning station #15. The employee failed to clean the prime container inside and out. 5. On 12-01-2021 at 8:55 AM, the Clinical Manager, Employee L was queried about the cleaning of the dialysis station. Employee L indicated that the prime container should be emptied and cleaned from the inside and outside when cleaning the station. 6. During an observation on 11-29-21 at 9:35 AM, the PCT, Employee N, was cleaning station #6. The employee failed to clean the prime container inside and out after emptying the container.		the Dialysis Station Education emphasis was placed on: · Cleaning and disinfected all work surfaces within the hemodialysis station with 1:100 bleach solution after completion of procedures; including but not limited to the prime bucket containers. · Ensure the surfaces are glistening wet and allow to air dry before placing the next patient into the hemodialysis station. Effective December 13, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on fully opening chairs and cleaning with 1:100 bleach solution per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. 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	

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	7. During an observation on 11-29-21 at 10:41 AM, the PCT, Employee F, was cleaning station #4. The employee failed to clean the prime container inside and out after emptying the container.		Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 30, 2021	
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	V 0128	On December 10, 2021, the Clinic Manager held a staff meeting and	12/30/2021

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	interview, the facility failed to obtain a Center for Medicare and Medicaid Services (CMS) waiver allowing for the exclusion of an isolation room for a facility that opened prior to October 14, 2008 in accordance with 42CFR 494.30 (a)(1)(i). Findings include: 1. On 11-29-2021 at 9:06 AM, during the flash tour, it was noted there were 16 dialysis stations. There was no isolation room. 2. On 11-29-2021 at 9:49 AM, during the entrance conference the Clinical Manager (CM), Employee L, was queried about the waiver for the isolation room. Employee L indicated they would provide this. 3. On 11-29-2021 at 2:46 PM, during the daily conference the DO, Employee M, was queried for the second time about the waiver for the isolation room. Employee M indicated they were in communication with corporate about the waiver. 4. On 11-30-2021 at 3:50 PM, the DO, Employee M, was queried for the third time about the waiver for the isolation room. Employee M indicated that they were still awaiting word from their corporate office. 6. On 12-01-2021 at 8:30 AM, the DO, Employee M, provided the Fresenius Kidney Care letter requesting application for the CMS waiver.		reinforced 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: · 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. · Marshall County received the	

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			initial certification on 7/18/2007. The clinic has not expanded modality services or physical capacity after February 2009 and had a Hepatitis B Transfer Agreement in place upon surveyor arrival dated 8/19/2015. 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 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	

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			another local ESRD facility which does provide isolation services. Marshall County received the initial certification on 7/18/2007. The clinic has not expanded modality services or physical capacity after February 2009 and had a Hepatitis B Transfer Agreement in place upon surveyor arrival dated 8/19/2015. 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 clinic does not recall indicating that a waiver was required. The Director of Operations applied for the Hepatitis B waiver per surveyor instructions on 11/30/2021. Effective December 13, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on ensuring patients who are Hepatitis B antigen positive (HBsAg+) dialyze under isolation precautions. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.	

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			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 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, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 30, 2021	
V 0147 Bldg. 00	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of			

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	Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters. II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients. VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections]. Based on observation, record review, and interview, the facility failed to ensure that staff instructed and confirmed the patients washed their access sites upon entering the facility prior to proceeding with skin asepsis for 5 of 6 observations (Patient # 2, 3, 10, 11, and 24) (Employee C, D, F, N) and 1 of 1 interview (Patient #20) conducted. Findings include:	V 0147	On December 10, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Assessment and Cannulation Education emphasis was placed on: · Cleaning and Assessment and Preparation of Access Site	12/30/2021

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FRESENIUS MEDICAL CARE NEPHROLOGY MARSHALL COUN	2855 MILLER DR STE 209 PLYMOUTH, IN 46563

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	1. On 12-01-2021 at 9:59 AM, a November 2021 Fresenius Kidney Care policy titled, "Access Assessment and Cannulation" was provided by the Director of Operations (DOO), employee M. The policy indicated but was not limited to, "...Prior to treatment ask the patient to wash access area with soap per hand hygiene procedures...". 2. During an observation on 11-29-2021 at 10:45 AM, the Licensed Practical Nurse (LPN), Employee C, failed to validate patient #2 had washed their access prior to assessing their access. 3. During an observation on 11-29-2021 at 11:24 AM, Employee C, failed to validate patient # 3 had washed their access prior to assessing their access. 4. During an observation on 11-29-2021 at 12:07 PM, the Patient Care Technician (PCT), Employee D, failed to validate patient #24 had washed their access prior to assessing their access. 5. On 12-01-2021 at 8:40 AM, the DOO (Director of Operations), Employee M was queried about the process for patients cleaning their access prior to moving forward to cannulation (the process of inserting the dialysis needles into the patients access) in which Employee M respondeded the staff should ensure the access site is cleaned prior to cannulation. 6. During an observation on 11-29-2021 at 10:30 AM, the Certified Clinical Hemodialysis Technician (CCHT), Employee N, was observed assisting patient #10 to station #6. Employee N, failed to instruct or confirm patient #10 had washed skin over her fistula or graft access site		prior to needle placement and cannulation. · Ensuring adequate preparation and assessment of the fistula or graft, · Prior to treatment, ask patient to wash access area with liquid soap for one minute, rinsing well. · Staff will wash access if patient is unable to clean their access. Effective December 13, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on ensuring patient's access are cleaned per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. 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	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152611	A. BUILDING 00 B. WING	12/01/2021

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	prior to proceeding with skin antisepsis. 7. During an observation on 11-29-2021 at 11:22 AM, the CCHT, Employee F, was observed assisting patient #11 to station #3. Employee F, failed to instruct or confirm patient #10 had washed skin over her fistula or graft access site prior to proceeding with skin antisepsis. 8. During an observation on 11-30-2021 at 11:20 AM, the CCHT, Employee F, was observed assisting patient #23 to the sink to wash the access site when the patient stated, "Why are you asking me to do this now? Is it because the state is here?" 9. During an interview on 12-01-2021 at 8:45 AM, when discussing observations of the patients and staff responsibilities instructing and confirming patients had washed access site prior to initiation, the Clinical Manager (CM), Employee L, and Employee M confirmed the staff should instruct and confirm the patients wash their access site upon entering facility prior to initiation of dialysis. 10. During a phone interview on 12-01-2021 at 9:45 AM, patient #20, when queried about staff asking the patient to wash his access site, the patient stated, "No. They do not ask you to do that here (at the facility)."		other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 30, 2021	
V 0402 Bldg. 00	494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public. Based on observation, record review, and	V 0402	On December 10, 2021, the Clinic Manager held a staff meeting and	12/30/2021

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	interview, the facility failed to ensure the safety of patients and staff were maintained for 3 of 3 survey days. Findings include: 1. On 11-30-2021 at 3:57 PM, an April 2021 Fresenius Kidney Care policy titled, "Storage of Supplies" was provided but the Clinical Manager (CM), employee L. The policy indicated but was not limited to, " All clean or sterile supplies... must be stored off the floor...". 2. On 12-01-2021 at 9:30 AM, a November 2021 Fresenius Kidney Care policy titled, "General Cleanliness and Infection Control Guidelines" was provided but the Director of Operations (DO), employee M. The policy indicated but was not limited to, "The purpose of this policy is to provide guidance for FKC staff... and maintain a clean, safe and aesthetic environment...All areas must be kept clean and organized...walkways must be kept free of debris... all cleaning supplies shall be stored in a designated area...". 3. On 11-29-2021 at 8:50 AM, upon entry to the dialysis treatment space there were nine cardboard boxes to the right of the door on the floor. The boxes were labeled "neck pillows". Patients enter this door to access the scale and clean sink prior to treatment. 4. On 11-29-2021 at 9:00 AM, during the flash tour, there were 6 cardboard boxes labeled "specimen trays" and one cardboard box holding wheelchair foot braces on the medical lab floor. The medical lab refrigerator was found to have gray "lint" particles on the bottom shelf. The shelf held a patient specimen tray with 12 lavender topped blood-filled tubes.		reinforced the expectations and responsibilities of the facility staff on policies: · Storage of Supplies · General Cleanliness and Infection Control Guidelines · Physical Security and Facility Access Education emphasis was placed on: · All clean or sterile supplies must be stored off the floor. · Clinic staff will ensure a clean, safe and aesthetic environment. · All clean or sterile supplies must be stored off the floor. · All areas must be kept clean and organized; walkways must be kept free of debris. · All cleaning supplies shall be stored in a designated area. · Restricted access must be maintained to prevent unwanted tampering with the water treatment equipment. Effective December 13, 2021, the Clinic Manager or designee will conduct storage audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Physical Environment Monitoring Tool. The focus will be maintaining a clean and safe environment per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and	

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	5. On 11-29-2021 at 9:12 AM, during the flash tour a bottle of commercial drain cleaner, 80% empty, was found on the treatment floor along the wall of windows. 6. On 11-29-2021 at 9:30 AM, during the flash tour the water room door was easily pushed open with a key padlock in place allowing entry without putting in a code to access the room. 7. On 11-30-2021 at 11:30 AM, during the water room tour with the Area Technical Operations Manager (ATOM), Employee P, the water room door was easily pushed open with a key padlock in place allowing entry without putting in a code to access the room. 8. On 12-01-2021 at 10:00 AM, the medical lab room refrigerator was observed to have dust-like material in it. The cardboard boxes remained on the floor. 9. On 11-30-2021 at 2:30 PM, the medical lab room was observed with the Clinical Manager (CM), Employee L. The cardboard boxes remained on the floor. Employee L was queried about the dust-like material in the refrigerator. Employee L indicated they did not know how the material would be there. 10. On 11-30-2021 at 11:30 AM, when queried about the lock on the water room door, Employee P indicated they did not pull the door closed tight enough to lock it. 11. On 12-01-2021 at 8:10 AM, when queried about the medical lab room refrigerator, Employee L indicated the medical lab room was not on the contracted cleaners list.		Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinic Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. 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, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 30, 2021	

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	12. On 12-01-2021 at 10:50 AM, when queried about the lock on the water room door, Employee P indicated that they would need to place a work order to correct the lock.			