STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152500	A. BUILDING 00 B. WING	11/10/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE INDIANAPOLIS	2480 N MERIDIAN ST INDIANAPOLIS, IN 46208

(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: 11-08, 11-09 and 11-10-2021 Facility #: 005147 CCN: 152500 ICHD census: 99 Home PD census: 25 Home HD census: 3 Total Census: 127 At this Emergency Preparedness survey, Fresenius Medical Care Indianapolis, 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 11/18/21 by Area 3	E 0000		
V 0000 Bldg. 00	This visit was for a CORE Federal recertification	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.

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	and complaint survey of an ESRD provider . Complaint: IN00344276: Unsubstantiated. No Federal deficiencies were cited related to the complaint. Survey dates: 11-08, 11-09 and 11-10-2021 Facility #: 005147 CCN#: 152500 ICHD census: 99 Home PD census: 25 Home HD census: 3 Total: 127 Quality Review Completed on 11/18/21 by Area 3			
V 0116 Bldg. 00	494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. -- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient. -- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a			

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	common clean area or used on other patients. Based on observation, record review and interview the facility failed to ensure the proper disinfection of non-disposable items (thermometer and stethoscope) over 2 of 3 observation days. (Employee: Q (three times), N (twice), P, I and G. Findings include: 1. On 11-10-2021 at 10:05 AM, the Director of Operations (DOO), employee D, provided a November 2020 policy titled, "Cleaning and Disinfection of the Dialysis Station". The policy indicated but was not limited to, "... all work surfaces shall be cleaned and disinfected .. after the completion of procedures...". 2. During an observation on 11-08-2021 at 8:30 AM, during the flash tour, the Patient Care Technician (PCT), employee Q was observed taking the stethoscope from the hanger at the entrance and moving to the isolation room. Employee Q used the stethoscope to listen to the access without cleaning the stethoscope bell prior to use. 3. During an observation on 11-08-2021 at 10:45 AM, the Registered Nurse (RN), employee N, was observed not cleaning the stethoscope after use for patient #1. As patient #1 left the treatment floor, employee N checked the patient's temperature with the thermometer at the exit. Employee N was wearing gloves to check the patients temperature. Employee N failed to clean the thermometer after use. 4. During an observation on 11-08-2021 at 11:15 AM, the PCT, employee P, was observed taking	V 0116	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Cleaning and Disinfection of the Dialysis Station Education emphasis was placed on: · Ensure the proper disinfection of non-disposable items, including but not limited to the thermometer and stethoscope. · All work surfaces shall be cleaned and disinfected after the completion of procedures. · Utilization of an appropriate EPA disinfectant such as 70% isopropyl alcohol wipes to clean the stethoscope and thermometer. · The disinfectant should be registered low or intermediate to avoid degradation of the stethoscope and thermometer. Effective November 29, 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 disinfecting non-disposable equipment after the completion of procedures. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and	12/09/2021

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	the temperature of patient #19 following the completion of their treatment. Employee P utilized the thermometer at the exit without wearing gloves. Employee P failed to clean the thermometer after use. 5. During an observation on 11-08-2021 at 11:20 AM, the RN, employee I, was observed taking the temperature of patient #20 following the completion of their treatment. Employee I utilized the thermometer at the exit without wearing gloves. Employee I failed to clean the thermometer after use. 6. During an observation on 11-09-2021 at 11:10 AM, the PCT, employee Q, was observed taking the temperature of patient #21 following the completion of their treatment. Employee Q utilized the thermometer at the exit without wearing gloves. Employee Q failed to clean the thermometer after use. 7. During an observation on 11-09-2021 at 11:35 AM, the PCT, employee Q, was observed taking the temperature of patient # 9 following the completion of their treatment. Employee Q utilized the thermometer at the exit without wearing gloves. Employee Q failed to clean the thermometer after use. 8. During an observation on 11-09-2021 at 11:40 AM, the PCT, employee G, was observed taking the temperature of patient #12 following the completion of their treatment. Employee G utilized the thermometer at the exit without wearing gloves. Employee G failed to clean the thermometer after use. 9. On 11-09-2021 at 3:05 PM, the Clinical Manager, employee C, was queried about the cleaning of the		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 9, 2021	

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	stethoscope and thermometer. Employee C indicated the basket that the thermometer sits in is considered a common area and does not need to be cleaned. Employee C indicated that if the equipment is used with staff with and without gloves, they should be cleaned between use.			
V 0119 Bldg. 00	494.30(a)(1)(i) IC-SUPPLY CART DISTANT/NO SUPPLIES IN POCKETS If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies. Do not carry medication vials, syringes, alcohol swabs or supplies in pockets. Based on observation, record review, and interview, the facility failed to ensure clean supplies were stored properly for 3 of 3 observations over 1 of 2 survey days. (Employee N) Findings include: 1. On 11-10-2021 at 10:05 AM, a February 2018 Fresenius Kidney Care policy titled, " Personal Protective Equipment" was provided by the Director of Operations, (DOO), employee D. The policy indicated but was not limited to, "... All personal protective equipment shall be removed prior to leaving the treatment area...a supply of clean, non-sterile gloves and a waste container shall be placed near each dialysis station...". 2. During an observation on 11-09-2021 at 8:15 AM, the Registered Nurse (RN), employee N was	V 0119	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Personal Protective Equipment Education emphasis was placed on: · Ensure staff do not carry gloves or any patient care supplies in pockets. · Ensure clean supplies are stored properly. Effective November 29, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one	12/09/2021

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	observed removing gloves from their pants pocket underneath their disposable gown to assess Patient # 3. 3. During an observation on 11-09-2021 at 10:40 AM, the RN, employee N was observed cleaning station #19. Employee N disposed of the dialysis tubing, emptied the prime container and failed to remove their gloves prior to returning to station #19. Employee N completed the cleaning, removed gloves, sanitized hands with the station sanitizer and donned new gloves by removing them from their pants pocket underneath their disposable gown. 4. During an observation on 11-09-2021 at 11:15 AM, the RN, employee N was observed moving from the nurse's desk to station # 15. Employee N removed gloves from their pants pocket underneath their disposable gown to review the settings at station #15 for patient # 14. 5. On 11-09-2021 at 3:05 PM, the Clinical Manager, employee C, was queried about the practice of storing gloves in their pockets while providing care on the treatment floor. Employee C indicated that gloves should never be stored in ones pockets.		month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on glove storage and usage 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 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	

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			Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: December 9, 2021	
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 7 observations over 2 of 3 survey days. (Employee: L, J, G, O, M) Findings include: 1. On 11-10-2021 at 10:05 A.M., a November 2020, Fresenius Kidney Care policy titled, " Cleaning and Disinfection of the Dialysis Station" was provided by the Director of Operations (DOO), employee D. 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...make the surface glisteningly (sic) wet and allow to dry...". 2. During an observation on 11-08-2021 at 10:25 AM, the Certified Clinical Hemodialysis Technician (CCHT), employee L and Patient Care	V 0122	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Cleaning and Disinfection of 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, dialysis chair arms, and chair sides while arms are fully opened. · Ensure the surfaces are glistening wet and allow to air dry before placing the next patient into the hemodialysis station.	12/09/2021

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	Technician (PCT), employee J were cleaning station #1. The employees failed to empty and clean the prime container inside and out as well as fully open the dialysis chair arms. The chair arms were not allowed to dry before closing. 3. During an observation on 11-08-2021 at 10:57 AM, the PCT, employee G, failed to empty and clean the prime container inside and out as well as fully open the dialysis chair arms. The chair arms were not allowed to dry before closing. 4. During an observation on 11-09-2021 at 11:05 AM, the PCT, employee O, failed to empty and clean the prime container inside and out as well as fully open the dialysis chair arms at station #15. The chair arms were not allowed to dry before closing. 5. During an observation on 11-09-2021 at 10:25 AM, the HHCT, employee M, failed to empty and clean the prime container inside and out as well as fully open the dialysis chair arms at station #3. The chair arms were not allowed to dry before closing. 6. During an observation on 11-09-2021 at 11:47 AM, the PCT, employee G, failed to empty and clean the prime container inside and out as well as fully open the dialysis chair arms at station #4. The chair arms were not allowed to dry before closing. 7. On 11-09-2021 at 3:10 PM, the Nurse Manager, employee C was queried about the cleaning of the dialysis station. Employee C indicated that the prime container should be emptied and cleaned from the inside and outside. The chair should be fully extended and allowed to dry.		Effective November 29, 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 cleaning all work surfaces within the hemodialysis station 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 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	

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			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 9, 2021	
V 0401 Bldg. 00	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. Based on observation and interview the facility failed to ensure the design and construction provides a safe environment for patients and staff as noted during the flash tour on 11-08-2021 and observation on 11-10-2021, 2 of 3 survey days. Findings include: 1. During the flash tour on 11-08-2021 at 8:30 AM, the water room appeared under construction. The garage door was open to the outside with no one in attendance. A bobcat (machine to dig trenches) was noted in the room opposite of the garage door. Construction workers were present digging trenches for the new water room location. The water room was open to the construction workers and people from the parking lot.	V 0401	On November 23, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Physical Security and Facility Access Education emphasis was placed on: · Ensure the clinic design and construction provides a safe environment for patients and staff. · Restricted access must be maintained to prevent unwanted tampering with the water treatment equipment. · The facility must be maintained to prevent unwanted	12/09/2021

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	2. During the flash tour on 11-08-2021 at 8:35 AM, the entry door for the Home Peritoneal Dialysis center was observed open at the bottom of the door. A 1 inch opening across the bottom of the door was present. 3. During a tour of the water room on 11-08-2021 at 9:39 AM, the garage door remains open to the exterior with the construction on going. There is none in attendance at the door. 4. On 11-10-2021 at 7:55 AM, the garage door to the water room remained open. Construction workers were observed going in and out of the entrance. There was an attendant sitting in a chair looking at their phone. 5. On 11-08-2021 at 9:39 AM, the Area Technical Operations Manager, employee R, indicated that construction of the water room began in October. The new water room construction requiring the use of the bobcat is to conclude on 11-10-2021 with all construction slated to be complete in December of 2021. 6. On 11-09-2021 at 2:45 PM, the Mar Con Construction Manager, employee AA, indicated that the construction of the water room requiring the use of the bobcat should be complete on 11-10-2021. Employee AA indicated another employee will be positioned at the door when the garage door is open.		entry by outside persons not involved in the daily operation of the clinic. · No exterior building door will be left unlocked unless under the continual supervision of a facility staff member. Effective November 29, 2021, the Clinic Manager or designee will conduct a security audit daily for one week, then weekly for two weeks, then monthly utilizing the Physical Environment Monitoring Tool. The focus will be on restricting access to water treatment equipment unless under direct supervision of facility staff. 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 other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution	

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			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 9, 2021	