STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152566	A. BUILDING 00 B. WING	04/19/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GREENFIELD	1051 N STATE ST GREENFIELD, IN 46140

(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		E 0000		
	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. Survey dates: 04-17, 04-18, and 04-19-2023 ICHD 12-month unduplicated census: 53 Home Peritoneal Dialysis census: 0 Home Hemodialysis census: 0 Total Census: 53 At this Emergency Preparedness survey, Fresenius Medical Care Greenfield, was found to have been in compliance with the Emergency Preparedness Requirements for Medicare and Medicaid participating providers and suppliers, 42 CFR 494.62. QR by Area 3 on 4-26-2023			
V 0000 Bldg. 00		V 0000		
	This visit was for a Federal CORE Recertification survey of an ESRD supplier conducted by the Indiana Department of Health. Survey dates: 04-17, 04-18, 04-19-2023 CCN: 152566			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Dawn Nelson	Administrator	05/04/2023

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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	ID: 11029 ICHD 12-month unduplicated census: 53 Home Peritoneal Dialysis census: 0 Home Hemodialysis census: 0 Total: 53 QR by Area 3 on 4-26-2023			
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 agency failed to ensure hand hygiene was performed per the agency's policy by staff as noted over 6 of 6 hand hygiene observations. (Registered Nurse (RN) 2 (four times)) (Patient #3 and Patient #11). Findings include: 1. Review of an agency document dated 03-17-2023, titled 'Hand Hygiene,' page 1 stated, "PURPOSE ... to prevent transmission of pathogenic microorganisms to patients and staff through cross contamination. RESPONSIBILITY All staff ... must follow the same requirements for hand hygiene." "... Hands Will Be ... Decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and	V 0113	FKC Greenfield Plan of Correction (Medicare ESRD Recertification Survey 4/19/23) Page 1 Fresenius Medical Care Indiana D/b/a Fresenius Kidney Care Greenfield Plan of Correction for Medicare ESRD Recertification Survey Date of Survey: 04/19/2023 V 113 IC-Wear Gloves/Hand Hygiene On 5/9/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: • Hand Hygiene Policy and Procedure	05/18/2023

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	water ...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 ... After contact with inanimate objects near the patient." 2. Review of and an agency document dated 9-26-2018, titled 'Hand Hygiene Procedure,' page 2 stated, "... Step 1. If gloves are worn, remove and discard ... 2. Apply alcohol-based hand rub to palm of one hand using amount recommended by the product manufacture ... for maximum effectiveness ... 3. Rub hands together covering all surfaces of hands and fingers until hands are dry ... Note: Duration of the entire procedure: 20-30 seconds." 3. Review of an agency document dated 2-14-2018, titled 'Personal Protective Equipment,' stated, "Personal protective equipment such as ... fluid resistant gowns and gloves will be worn to protect and prevent employees from blood or other potentially infectious materials to pass through to or to reach the employee's skin ... or workclothes when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis ... and centrifugation of blood). Page 2 stated, "Disposable gloves must be used: when holding access bleeding sites ... When performing venipunctures or other vascular access procedures ... When touching patients during activities with potential exposure to bloodborne pathogens or other infectious material ... When touching any part of the dialysis machine or equipment at the dialysis station ... Change gloves and practice hand hygiene between each patient and /or station to prevent cross-contamination ... Remove gloves and wash hands after each patient		• Personal Protective Equipment Emphasis was placed on: • Staff should change gloves and practice hand hygiene between each patient and/or station to prevent cross-contamination. • Hands will be: o Decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water ¿ 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 · ¿ Immediately after removing gloves ¿ After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled ¿ After contact with inanimate objects near the patient. When moving from a contaminated body site to a clean body site of the same patient ¿ After contact with the dialysis wall box, concentrate, drain, or water lines ¿ After contact with other objects within the patient station or treatment space • Patients should perform hand hygiene if able, prior to and after	

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	contact ... use of waterless antiseptic hand rub is acceptable ... Avoid touching surfaces with gloved hands that will be touched with ungloved hands." 4. During an observation on 4-18-2023 at 3:02 PM, Registered Nurse (RN) 2, was observed at station #8 preparing to discontinue the dialysis treatment for Patient #23. RN 2, with gloved hands, was typing on the keyboard of the dialysis machine, reached over and adjusted the mask for Patient #23 which had dropped down below the patient's nose, then returned to typing on the keyboard. RN 2, with the same gloves on, then exchanged saline bags on the IV pole attached to the dialysis machine. The nurse then picked up a saline syringe from the chairside tray, removed the cap, pushed the air out, replaced the cap, and set the syringe back down on the tray. RN 2 removed a blanket which was covering the patient, folded it, and placed in patient's bag, doffed gloves, performed hand hygiene, donned new gloves, then removed a neck pillow from the patient. With same gloves still in place, RN 2 used both hands to firmly push down on the foot rest of the recliner, to aide the patient in returning to an upright position. The nurse then turned to the patient's access site, a Central Venous Catheter CVC (a vascular access device inserted below the collar bone) and took each lumen of the CVC in hand. After disconnecting blood lines, scrubbed each hub, later applied sterile caps, discarded the used supplies, returned to the keyboard, touched the patient's mask again, returned to the keyboard and then walked away from the station. The nurse failed to doff gloves and perform hand hygiene at appropriate intervals during the discontinuation of dialysis. 5. On 4-19-23 at 11:28 AM, when informed of hand		each dialysis treatment. o As needed, direct patient care staff will demonstrate how to operate the sinks, demonstrate hand washing to patients who are able to perform hand washing, and explain risk of contamination with regard to their vascular access and hands to all patients. On 5/12/2023 100% of all patients will be re-educated on hand hygiene with documentation of education noted in each patient's EMR. Those patients absent on the day of education will be re-educated on their first treatment back at the facility with documentation noted in the EMR. Effective 5/10/2023, the Clinical Manager or designee will conduct weekly audits with focus ensuring hand hygiene is performed per facility policy by staff and patients utilizing Infection Control Audit Tool for four weeks or until 100% compliance is achieved. Once compliance is sustained, the Governing BodyFKC Greenfield Plan of Correction (Medicare ESRD Recertification Survey 4/19/23) Page 2 will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Tool per QAI calendar. The Medical Director will review	

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	hygiene and infection control breaches observed on the treatment floor, the Area Team Leader indicated there was an expectation the RN's working on the treatment floor would have noticed and corrected these practices. 6. During an observation on 04-17-2023 at 9:15 AM, Patient #3 completed their dialysis treatment and held pressure with their gloved right hand. Patient #3 was not offered and did not complete hand hygiene when exiting the treatment floor to entering the waiting room and re-entering the community. 7. During an observation on 04-17-2023 at 2:10 PM, Registered Nurse (RN) 2 moved a chair while wearing gloves to station #9 to initiate treatment for Patient #9. RN 2 did not remove their gloves or perform hand hygiene prior to cannulating the right upper extremity (RUE) of Patient #9. 8. During an observation on 04-17-2023 at 2:35 PM, RN 2 documented on the dialysis machine at station #7. While wearing gloves RN 2 moved the biohazard container to the station, proceeded to reinfuse the extracorpeal blood, decannulated (remove the dialysis needles) of Patient #10. RN 2 failed to remove their gloves and perform hand hygiene prior to the decannulation process. 9. During an observation on 04-17-2023 at 2:45 PM, RN 2 removed their gloves and applied new gloves without performing hand hygiene. RN 2 proceeded to apply tape to Patient #11's access site of their left upper extremity. Patient #11 was escorted off the treatment floor by RN 2. No hand hygiene was offered to the patient and Patient #11 did not was hands prior to returning to the waiting room and the community. 10. During an observation on 04-18-2023 at 9:45		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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring	

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	AM, RN 2 was observed moving a wheelchair with gloved hands. While wearing the same gloves RN 2 used their stethoscope to listen to the Patient #19's access site at station #3. RN 2 did not change their gloves or perform hand hygiene prior to cannulating (process of inserting the dialysis needles) the patient. RN 2 wore the same gloves while cleaning their stethoscope.		documentation are available for review at the clinic. Completion 05/18/2023.	
V 0543 Bldg. 00	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on record review and interview, the agency failed to ensure nursing assessments were completed timely according to agency policy in 4 of 7 patient treatment records. (Employee: Registered Nurse (RN): 2 (seven times) ,1 (three times), and 4 (one time)) (Patients: #3, #5, #6, and #23) Findings include: 1. A review of an agency policy dated 11-01-2021, titled "Nursing Supervision and Delegation," indicated but was not limited to ... "Policy, The registered nurse must evaluate each patient preferably within an hour ..." 2. On 04-18-2023 at 11:30 AM a clinical record review of Patient #3 was completed. The review indicated 4 of 10 treatment records evidenced the Registered Nurse (RN) assessment failed to meet the one hour limit determined by the agency's policy. The following records indicated:	V 0543	V 543 POC-Manage Volume Status On 5/9/2023, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: • Nursing Supervision and Delegation Emphasis was placed on: • The registered nurse must evaluate each patient preferably within an hour or according to state requirements to: o Confirm identify o Review the patient's condition. o Review accuracy and completeness of treatment and patient data o Review patient treatment prescription is being followed. o Confirm that the correct vascular	05/18/2023

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	A. On 03-31-2023 at 05:03 AM, approval to start the dialysis treatment of Patient #3 was given. RN 2 completed the assessment at 8:43 AM. B. On 04-05-2023 at 04:50 AM, approval to start the dialysis treatment of Patient #3 was given. RN 2 completed the assessment at 7:29 AM. C. On 04-14-2023 at 05:22 AM, approval to start the dialysis treatment of Patient #3 was given. RN 1 completed the assessment at 07:27 AM. D. On 04-14-2023 at 05:03 AM, approval to start the dialysis treatment of Patient #3 was given. RN 1 completed the assessment at 08:43 AM. 3. On 04-18-2023, the Area Team Lead, Administrator 2 was queried regarding the process for nursing assessments. Administrator 2 indicated the nursing assessment should be completed within an hour of a treatment's initiation and the above patients had their assessments 2-3 hours or more after the initiation of their treatment.4. On 04-18-2023, a clinical record review of Patient #5 was completed. The review indicated 2 of 11 treatment records evidenced the Registered Nurse (RN) assessment failed to meet the one hour limit determined by the agency's policy. The following records indicated: A. On 03-25-2023 at 10:36 AM, the dialysis treatment for Patient #5 was started. RN 2 completed the assessment at 12:24 PM. E. On 04-11-2023 at 10:16 AM, the dialysis treatment for Patient #5 was started. RN 2 completed the assessment at 12:42 PM.		access is being used, and that the access is visible. Observe patient's response to treatment. o Verify machine safety checks have been completed. o Talk to the patient to elicit information such as changes in condition, response to treatment, new injuries, information/education needs or complaints, satisfaction with care. Effective 5/10/2023, the Clinical Manager or designee will conduct weekly audits with focus on ensuring nursing assessments are completed timely according to facility policy utilizing Treatment Sheet Audit Tool for four weeks or until 100% compliance is achieved. Once compliance is sustained, the GoverningFKC Greenfield Plan of Correction (Medicare ESRD Recertification Survey 4/19/23) Page 3 Body will decrease frequency to resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the Clinic Audit Checklist Tool per QAI calendar. 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	

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	5. On 04-18-2023, the clinical record for Patient #6 was reviewed. The review indicated 3 of 11 treatment records evidenced the Registered Nurse (RN) assessment failed to meet the one hour limit determined by the agency's policy. The following records indicated: A. On 04-04-2023 at 11:00 AM, the dialysis treatment for Patient #6 was started. RN 2 completed the assessment at 12:51 PM. B. On 04-13-2023 at 10:31 AM, the dialysis treatment for Patient #6 was started. RN 1 completed the assessment at 11:48 AM. C. On 04-11-2023 at 10:43 AM, the dialysis treatment for Patient #6 was started. RN 2 completed the assessment at 12:01 PM. On 04-19-2023, the clinical record review of Patient #6 was continued. The review evidenced the Registered Nurse's (RN) assessment prior to first treatment for a patient new to dialysis failed to meet the requirement. The following record indicated: On 03-04-2023 at 11:02 AM, the initial dialysis treatment of Patient #1 was started. RN #4 completed the pintail assessment at 12:28 PM, after the treatment had been initiated. 6. On 04-19-2023 the clinical record for Patient #23 was reviewed. The review indicated 1 of 10 treatment records evidenced the Registered Nurse (RN) assessment failed to meet the one hour limit determined by the agency's policy. The following records indicated on 09-20-2022 at 07:07 AM, the dialysis treatment for Patient #23 was started. RN 2 completed the assessment at 8:22 AM.		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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 05/18/2023	

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	7. During an interview on 04-19-2023 at 1:43 PM, when queried as to when the nurse should have a patient's initial assessment completed before the first dialysis treatment has been initiated, the Area Team Leader indicated this should be done "prior to, for the first treatment."			