STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152526	A. BUILDING 00 B. WING	12/09/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE KOKOMO	2350 S DIXON RD STE 450 KOKOMO, IN 46902

(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 State Department of Health in accordance with 42 CFR 494.62. Survey Date: 12/9/21 Facility #: 005168 Provider #: 152526 Census = 113 At this Emergency Preparedness survey, Fresenius Medical Care Kokomo was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.	E 0000		
V 0000 Bldg. 00	This visit was a Federal CORE ESRD Recertification survey. Survey dates: December 7, 8, 9; 2021 Facility #: 005168 Provider #: 152526 In-Center Census: 77 Home Therapy Census: 36 Total Patients all Modalities: 113	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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V 0240 Bldg. 00	494.40(a) BICARB DISTRIBUTION SYS-USE OF UV 5.5.4 Bicarbonate concentrate distribution systems: use of UV UV irradiation devices that are used to control bacteria proliferation in the pipes of bicarbonate concentrate distribution systems should be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm and provides a dose of radiant energy of 30 milliwatt-sec/cm2. The device should be sized for the maximum anticipated flow rate according to the manufacturer's instructions and be equipped with an on-line monitor of radiant energy output that activates a visual alarm indicating that the lamp should be replaced. Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer's instructions to maintain the recommended radiant energy output. Disinfection of the bicarbonate concentrate distribution system should continue to be performed routinely. Based on observation, record review, and interview, the agency failed to ensure that pH and conductivity was tested via the phoenix meter before initiation of dialysis for 2 of 2 staff observations (Patient Care Technicians C and D). Findings include: 1. A document titled "pHoenix Meter, pHoenix XL," indicated "Return sample to station area to perform test ... If using a Tri-Station cart it can be placed in treatment area to facilitate measurements but at a distance from machines to prevent cross contamination ... The pHoenix meter's internal cell must be rinsed between sample measurements with RO [Reverse Osmosis] Water ... Rinse meter with RO water after each measurement."	V 0240	On December 27, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies and procedure: · Checking Conductivity and pH of Final Dialysate Policy · pHoenix Meter, pHoenix XL and TriStation and Maintenance Policy · Checking Conductivity and pH of Final Dialysate with the Myron L DI Dialysate Meter Procedure Education emphasis was placed on:	01/08/2022

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	2. During an observation on 12/7/21 at 12:25 PM at dialysis station 20, Patient Care Technician C, was observed preparing dialysis station and initiating dialysis with a new patient. Employee failed to use the phoenix meter to test pH and conductivity prior to the initiation of dialysis. 3. During an observation on 12/7/21 at 1:05 PM at dialysis station 4, Patient Care Technician D, was observed preparing dialysis station and initiating dialysis with a new patient. Employee failed to use the phoenix meter to test pH and conductivity prior to the initiation of dialysis. 4. During an interview on 12/9/21 at 2:35 PM, when asked if a water conductivity test needed to be done before each patient is started on their dialysis treatment, Clinical Manager A confirmed, "Yes."		· Ensure that pH and conductivity is tested via the phoenix meter OR Myron L DI Dialysate Meter prior to the initiation of hemodialysis treatment; Kokomo utilizes a Myron-L meter to verify dialysate pH and conductivity. · The dialysate range must be verified with an instrument at which the test method can display pH and conductivity values within the Association for the Advancement of Medical Instrumentation (AAMI) recommendation. · The final dialysate pH and conductivity must be tested prior to each patient's treatment to verify the value is within the set parameters. · If the dialysate pH and conductivity is not within or equal to the set parameters, the reason must be investigated and reported to the clinical manager, charge nurse, team leader. Effective January 3, 2022, the Clinical Manager or designee conduct dialysate pH and conductivity audits daily for one week, then five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Patient Safety Monitoring Tool. The focus will be on verifying dialysate pH and conductivity prior to initiation of hemodialysis treatment per policy. Once 100% compliance is	

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			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 Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: January 8, 2022	

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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 and interview, the dialysis facility failed to ensure a safe physical environment to ensure the safety of all patients and the staff were maintained and failed to have a policy on machine replacement and safety of the environment within the clinic. Findings include: 1. During an observation on 12/7/21 at 9:45 AM, multiple areas under and surrounding the wall boxes on multiple stations were noted to be leaking a white, fuzzy-appearing substance. Additionally, the floors surrounding all dialysis stations had white fluid stains surrounding them. 2. During an observation on 12/9/21 at 2:11 PM, the dialysis machine at station 6 was observed to be leaking fluid from the back of the machine. The wall box at this station was observed to have condensate in the box and was leaking down the wall and on to the floor. 3. During an observation on 12/9/21 at 2:11 PM, the chair at station 7 was observed to not latch closed. The facility placed the chair right beside a pillar to help keep the chair pushed close. 4. During an observation on 12/9/21 at 2:11 PM, the floor surrounding station 10 was noted to have a puddle of water on it. 5. During an observation on 12/9/21 at 2:11 PM,	V 0402	On December 27, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·Housekeeping Policy · Equipment Installation, Operation, Maintenance, Repair, and Disposal Education emphasis was placed on: ·Ensure a safe physical environment for the safety of all patients and the staff is maintained. ·Ensure all staff is aware of policies related to machine replacement and safety of the environment within the clinic. ·Ensuring the patient treatment floor is cleaned appropriately, free of debris, and fluid stains, including but not limited to white crystallization on wall boxes. ·Ensure dialysis equipment, including but not limited to hemodialysis machines and patient treatment chairs, are maintained to provide safe and adequate care without leaks and proper chair closing. ·Maintaining a program to ensure that all equipment is	01/08/2022

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	the floor under the wall box at station 12 was observed to have a fuzzy-appearing corroded substance on it. 6. During an interview on 12/9/21 at 1:00 PM, when asked if the clinic had a policy on when to replace their dialysis machines, Employee E indicated, "No." 7. During an interview on 12/9/21 at 2:35 PM, when asked if the clinic had a plan to address the environmental issues at the clinic, Administrator B indicated, "A new cleaning crew has been hired to replace the current one. They start January 1, 2022."		maintained and operated in accordance with the manufacturer's recommendations. ·Prompt cleaning of standing water to ensure patient and staff safety. Effective January 3, 2022, the Clinic Manager or designee will conduct physical plant audits daily for one week, then 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 on maintaining a safe and functional treatment environment. 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	

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			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: January 8, 2022	
V 0407 Bldg. 00	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). Based on observation, record review, and interview, the agency failed to ensure site access was always visible for 2 of 2 station observations for 2 of 22 station observations (#8, 16). Findings include: 1. A policy titled "Safety Checks," indicated " ...The vascular access site, blood line connections and the patient's face should always be visible throughout the dialysis treatment ...." 2. During an observation on 12/9/21 at 9:00 AM, the patient at station 8's access site was not visible.	V 0407	On December 27, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Patient Monitoring and Safety Checks During Hemodialysis Treatment Education emphasis was placed on: · All patient connections are secure and visible at all times. · All patients must be under visual observation by clinical staff during treatment. · Ensure access remains	01/08/2022

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	3. During an observation on 12/9/21 at 9:00 AM, the patient at station 16's access site was not visible. 4. During an interview on 9/1/21 at 4:30 PM, when asked if access sites needed to be visible at all times, Clinical Manager A indicated "yes."		uncovered throughout the treatment. · Patients will not cover dialysis access or bloodlines with blankets or clothing. Effective January 3, 2022, the Clinical Manager or designee will conduct access visibility audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Patient Safety Monitoring Tool. The focus will be on access observations and patient safety checks. 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,	

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			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: January 8, 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 facility policies were followed to ensure drawn up parenteral medications were administered by the person who drew up the medications and failed to ensure opened medication bottles were labeled with an open date, which had the potential to affect all patients in the facility. Findings include: 1. A document titled "Medication Preparation and Administration," indicated, " ...The qualifications of medication administration are as follows ... The person who prepares the medication must be the	V 0715	On December 27, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Medication Preparation and Administration 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	01/08/2022

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	person who will administer the medication ...." 2. A cabinet containing medications was observed on 12/7/21 at 10:00 AM. A multi-dose bottle of calcitriol 0.5 mg medication bottle was open and failed to contain an open dated marked on it. Additionally, 2 pre-set medication cups with medications in them were observed. One medication cup contained 2 orange and 1 green pill with a label stuck to the cup that indicated the name of patient was #12 with the medication names vitamin D and cinacalcet on it. The second medication cup contained 1 orange and 1 green pill with a label stuck to the cup that indicated the name of patient was #13 with the medication names vitamin D and cinacalcet on it. Lastly, the medication refrigerator which contained bottles of liquacel contained 2 prefilled cups of liquid with no label or patient's name on it. 3. During an observation on 12/7/21 at 12:00 PM, Patient Care Technician E was observed initiating treatment on a patient at station 7. The staff member brought all supplies needed, along with pre-drawn medications. 4. During an observation on staff was observed on 12/7/21 at 12:20 PM, Patient Care Technician F was observed initiating treatment on a patient at station 3. The staff member brought all supplies needed, along with pre-drawn medications. 5. During an observation on staff was observed on 12/7/21 at 12:35 PM, Patient Care Technician E was observed initiating treatment on a patient at station 5. The staff member brought all supplies needed, along with pre-drawn medications. 6. During an observation on staff was observed on 12/7/21 at 12:40 PM, Patient Care Technician F		patients in the facility. · Ensure drawn up parenteral medications are administered by the person who drew up the medications. · Ensure opened medication bottles are labeled with an open date. Effective January 3, 2022, the Clinical Manager or designee will conduct medication preparation and administration audits daily for one week, then five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Patient Safety Monitoring Tool. The focus will be on medication administration 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	

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	was observed initiating treatment on a patient at station 8. The staff member brought all supplies needed, along with pre-drawn medications. 7. During an interview on 12/9/21 at 2:35 PM, when asked if multi-dose medications needed to be marked with an open date, Clinical Manager A confirmed, "Yes. When asked what happened if a staff is unable to start a patient, that they've been assigned to, on dialysis, but are unable to due to attending to another patient, what happens, Clinical Manger A indicated, "The nurse can assist and can give the patients medications as well." When asked if there was a policy on who gives medications that have been drawn up, Administrator A indicated "Its best practice."		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: January 8, 2022	