STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152588	A. BUILDING 00 B. WING	03/04/2025

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE IRVINGTON	1740 INDUSTRY DRIVE INDIANAPOLIS, IN 46219

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E 0000 Bldg. 00	An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62. Survey Dates: 03/03/2025 and 03/04/2025 Active Census: 75 At this Emergency Preparedness survey, FMC Irvington was found out of compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. QR by Area 3 on 3-07-2025.	E 0000		
E 0003 Bldg. 00	494.62 Establishment of the EP Program Dialysis Based on observation, record review, and interview, the facility failed to ensure the comprehensive Emergency Preparedness (EP) program met all requirements to meet the health, safety, and security needs of their staff and patient population (E-0003), failed to develop the emergency plan based on and documented facility -based and community-based risk assessment using an all-hazards approach (E-0006), failed to collaborate with local/regional officials to ensure the local officials are aware of dialysis facility needs in an emergency (E-0009), failed to ensure emergency equipment are not expired (E-0028), failed to ensure a communication plan is in place and updated annually (E-0029), and failed to perform annual emergency preparedness testing (E-0039) for 1 of 1 standalone dialysis facility .	E 0003	E-003 The Governing Body of this facility acknowledges its responsibility to ensure the facility maintains an emergency preparedness program meeting the safety needs of our patient population. The Governing Body on, 3/11/2025, reviewed the Statement of Deficiencies and developed the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The Governing Body began meeting weekly beginning	04/03/2025

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Kerrey Thornton	Director of Operations	03/21/2025

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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	The cumulative effect of these systemic problems resulted in the facility being found out of compliance with the condition, Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. Findings include: 1. A review of a Fresenius Kidney Care policy dated 02/03/2025 titled "Emergency Medications, Equipment and Supplies" indicated but was not limited to, " ... An emergency evacuation box must ... Be checked monthly or after use for contents, expiration dates ..." A review of a Fresenius Kidney Care document revised 08/02/2017 and titled "Emergency Disaster Responsibility Guidelines" indicated but was not limited to, " ... Prepare the Hazard Vulnerability Assessment for each facility ... Update each facility's disaster plan and emergency contact information directory ... Conduct a table top drill, Document Drills ... ensure the availability of disaster assets ... Clinical Manager ... Participate in the completion of the Hazard Vulnerability Assessment ... Maintain current listings of patients and staff including local contact, emergency contact, and evacuation information. 2. During a review of the emergency preparedness suitcase on 03/03/2025 at 10:30 AM, observed the following: a box of 200 size large exam gloves had an expiration date of 05/2022, a box of 200 size small exam gloves had an expiration date of 08/2022, 1 box of medical face masks had an expiration date of 05/22/2023, 100 alcohol prep pads had an expiration date of 11/2023, 1 bottle of hand sanitizer had an expiration date of 03/2024,		3/18/2025 to review the results of the progress on the Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The Governing Body will determine when the frequency of these meetings may be reduced to the regular quarterly schedule. Effective immediately: • The Home Therapy Program Manager will analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAPI Committee. • A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAPI (Quality Assessment and Performance Improvement) agenda. • The QAPI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues. • The Director of Operations (DO) will present a report on the Plan of Correction data and all actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. • The Governing Body, at its	

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	22 - 4"x4" non-woven sponges had an expiration date of 11/2020, 2 - 2"x2" non-woven sponges had an expiration date of 11/2020, 2 - blood collection kits had an expiration date of 03/31/2023, and 2 - 3 mL syringes with 20 G needles had an expiration date of 09/30/2023. During an interview on 03/03/2025 at 10:45 AM, the CM indicated Person 3 was responsible for reviewing the EP suitcase and Person 3 was not looking at the supplies if there were expired items. 3. A review of the Emergency Preparedness (EP) Binder revealed the following: A Fresenius Kidney Care document dated April 2021 - V9 titled "FKC Facility Emergency Information Directory" indicated but was not limited to, "Director of Operations / Area Manager Person 2". A Fresenius Kidney Care document dated June 2017 and titled "FKC Emergency Disaster Staff Contact Information Sheet". A facility document revised 12/2008 and titled "Emergency Shelter List by County". A review of a Fresenius Kidney Care document dated 10/03/2012 and titled "Irvington Home Facility Specific Fire Safety Plan". A review of a facility document dated 10/04/2018 and titled "Dialysis Facility Incident After Action Review / Improvement Plan" indicated but was not limited, " ... incident active shooter ...". A facility document dated 09/25/2024 and titled "Emergency Disaster Patient Contact List". The EP binder failed to evidence an updated "Emergency Disaster Patient Contact List" The EP binder failed to evidence annual review and revision, a communication plan, and documented facility-based and community-based risk assessment using an all-hazards approach.		meeting of (3/11/2025), designated the Director of Operations (DO)to serve as Plan of Correction Monitor and provide additional oversight. They will participate in QAPI and Governing Body meetings. This additional oversight is to ensure the ongoing correction of deficiencies cited in the Statement of Deficiency through to resolution as well as ensure the Governance of the Facility is presented current and complete data to enhance their governance oversight role. Minutes of the Governing Body and QAPI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction and oversight and the QAPI Committees ongoing monitoring of facility activities. These are available for review at the facility. The responses provided for E006, E0009, E0028, E0029 and E0039 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies cited within this Condition are corrected to ensure ongoing compliance. E-006 On 3/13/2025, the Director of	

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	During an interview on 03/03/2025 at 2:13 PM, the CM indicated "it's not real updated" while providing the emergency preparedness binder. During an interview on 03/03/2025 at 4:07 PM, the CM indicated the facility-based and community-based risk assessment using an all-hazards approach was not printed off and included in the binder. When queried about the document titled "FKC Facility Emergency Information Directory," the CM indicated the documented Director of Operations needed changed, the overall document needed updated, and the document should be updated annually. When queried about the patient list in the EP binder, the CM indicated the patient list should be updated quarterly. When queried about the revision date of the document titled "Emergency Shelter List By County," the CM indicated "my whole book needs updated". When queried about the fire plan dated 2012, the CM indicated the fire plan remains the same but should be reviewed annually and dated to reflect. When queried about emergency preparedness testing, the CM indicated the facility had not completed testing in a couple of years. When queried about the communication plan the CM indicated the order they call staff is dependent on what the scenario is. When queried if there was a call tree, the CM indicated they were unclear if a call tree and questioned the Director of Operations. The Director of Operations confirmed there is a call tree. When queried how often a communication plan should be reviewed, the CM indicated annually.		Operations, and Clinical Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. • Guidelines for Emergency Preparedness Emphasis will be placed on: ¿ The Interdisciplinary Team (including the Medical Director) led by the DO will annually complete the Hazard Vulnerability Assessment (HVA) spreadsheet identifying hazardous events that may affect clinic operations. The DO should ensure facilities in close proximity have similar HVAs. ¿ The Home Therapy Program Manager will participate in the completion of the Hazard Vulnerability Assessment. On 3/11/2025 the Home Therapy Manager placed the updated Hazard Vulnerability Assessment spreadsheet in the Emergency Preparedness binder. Effective 3/12/2025, the Director of Operations will conduct monthly audit with focus on ensuring the Emergency Preparedness binder is updated, as required, utilizing specific plan of correction Audit Tool for 3 months and then an additional 3 months or until 100% compliance is achieved. The Governing Body will determine on-going frequency	

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			of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Home Therapy Program Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by	

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			the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/03/2025. E-009 On 3/13/2025, the Director of Operations, and Home Therapy Program Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. • Guidelines for Emergency Preparedness Emphasis will be placed on: ¿ The DO will contact their local Emergency Operations Center (EOC) or similar agency to: o Understand the agency's capabilities and capacities o Share our capabilities and capacities o Discuss participating in a community-based drill they are running annually per procedure, the facility will contact their local disaster management agency to ensure that the agency is aware of the dialysis facility's presence in the community in the event of an emergency. On 3/11/2025, the Director of Operations, placed the updated	

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			Emergency Operations Center (EOC) Letter in the Emergency Preparedness binder. Effective 3/12/2025, the Director of Operations will conduct monthly audit with focus on ensuring the Emergency Preparedness binder is updated, as required, utilizing specific plan of correction Audit Tool for 3 months and then an additional 3 months or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Home Therapy Program Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting	

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			through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/03/2025. E-028 On 3/13/2025, the Director of Operations, and Home Therapy Program Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. • Emergency Medications, Equipment and Supplies Emphasis will be placed on: • An emergency evacuation box must: • Be available to grab in case of	

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			fire or the immediate need to evacuate the clinic. • Contain all patient and staff emergency contact information. • Be checked monthly or after use for contents, expiration dates and cleanliness. • All staff must know the location of the evacuation box and who is responsible to grab it during an emergency evacuation. • An itemized log must be kept indicating the contents and expiration dates of contents. Items approaching expiration must be reordered and replaced prior to the actual expiration date. On 3/12/2025, the Home Therapy Program Manager checked the Evacuation Box cart for expired supplies/ and medications per policy. On 3/13/2025, the Director of Operations orientated staff to the location of the Evacuation Box and educated the staff on the frequency for monitoring. Effective 3/12/2025, the Director of Operations will conduct monthly audit with focus on ensuring the Emergency Evacuation Box is checked for expired supplies/ and medications, as required, utilizing Specific Audit Tool for 3 months and then an additional 3 months or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits	

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			based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Home Therapy Program Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is	

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			effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/03/2025. E-0029 On 3/13/2025, the Director of Operations, and Home Therapy Program Manager (HTPM), held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. • Guidelines for Emergency Preparedness Emphasis will be placed on: ¿ The facility must develop a communication plan for all patients (in-center and home). ¿ This plan includes the following: o Create and maintain staff, patient and facility emergency information contact lists: ¿ Quarterly, the Director of Operations/Area Manager or designee will review and update: The FKC Facility Emergency Information Directory ¿ Quarterly, the HTPM will review and update: ¿ The Emergency and Disaster Staff Contact Information Sheet ¿ The Emergency and Disaster Patient Contact Information Sheet	

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			¿ A current copy of the emergency lists will: ¿ Be kept locked in the emergency supply boxes, or cart. ¿ Be sent to the facility's Director of Operations (DO) ¿ The DO will retain copies for each facility they manage ¿ The patient contact lists contain PHI and must be maintained in a secure location such as on a laptop or in a locked location • The Home Therapy Program manager will ensure the following items are updated annually and as needed: The FKC Facility Emergency Information Directory FKC Emergency Shelter List by County The Facility's communication plan/call tree The Facility Specific Fire Safety Plan On 3/13/2025, the Director of Operations, placed the updated Communication plan in the Emergency Preparedness binder. Effective 3/12/2025, the Director of Operations will conduct monthly audit with focus on ensuring the Emergency Preparedness binder is updated, as required, utilizing specific plan of correction Audit Tool for 3 months and then an additional 3 months or until 100% compliance is achieved. The	

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			Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Home Therapy Program Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the	

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			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 QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/03/2025. E-039 On 3/13/2025, the Director of Operations, and, Home Therapy Program Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. • Guidelines for Emergency Preparedness Emphasis will be placed on: • Annually, each facility must participate in a community-based disaster drill. If unable to participate, document who you contacted in the community and why the clinic was unable to participate on the Facility Specific Disaster Safety Plan form. If the EOC or similar agency has not performed a community-based drill, or it was missed for a particular year, the DO should coordinate a dialysis facility area-based drill. • The Governing Body will: • Review and approve the Facility Specific Disaster Safety plan	

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			initially and annually. • Review the FKC Facility Emergency Information Directory is complete and current. By 3/20/2025, Director of Operations will conduct a facility Table-Top Drill on “Ice Storm”, with an after action review for all staff. Table-Top materials with signature page will be located at facility and available for review upon request. Effective 3/12/2025, the Home Therapy Program Manager will conduct monthly audits utilizing specific plan of correction audit tool for 3 months, and then an additional 3 months or until 100% compliance is achieved. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAPI calendar. Monitoring will be done through the specific plan of correction audit tool. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Home Therapy Program Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly.	

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	152588	A. BUILDING 00 B. WING	03/04/2025

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			The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/03/2025	
V 0000 Bldg. 00	This visit was for a CORE Federal Recertification survey of an ESRD provider.	V 0000		

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	Survey Dates: 03/03/2025 and 03/04/2025 Census by Service Type: In-Center Hemodialysis: 0 Home Hemodialysis: 22 Peritoneal Dialysis: 53 Total Census: 75 Isolation: N/A FMC Irvington was found out of compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. Abbreviations RN Registered Nurse ICHD In-Center Hemodialysis PCT Patient Care Technician HHD Home Hemodialysis FA Facility Administrator PD Peritoneal Dialysis MD Medical Doctor CVC Central Venous Catheter RD Registered Dietician CM Clinical Manager MSW Masters Social Worker LPN Licensed Practical Nurse CCHT Certified Clinical Hemodialysis Technician QR by Area 3 on 3-07-2025.			
V 0117 Bldg. 00	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Based on observation, record review, and interview, the facility failed to ensure supplies were not stored under sinks for 6 of 6 patient exam	V 0117	V117 On 3/13/2025, Home Therapy Program Manager held a staff	04/03/2025

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	rooms with a stand alone home dialysis program. Findings Include: 1. A review of a Fresenius Kidney Care policy dated 11/04/2024, titled "General Cleanliness and Infection Control Guidelines," indicated but was not limited to, " ... The purpose of this policy is to provide guidance for the FKC staff on preventing the spread of infectious disease and maintaining a clean, safe, and aesthetically pleasant environment for patients, staff, and visitors ... Clean supplies may not be kept under dirty sinks ..." 2. During a flash tour of the facility on 03/03/2025 at 9:40 AM, the following observations were made: An observation in Patient Exam Room 3 evidenced a small trash can under the sink without a cabinet under it. An observation in Patient Exam Room 4 evidenced a small trash can and a patient scale under the sink without a cabinet under it. 3. During a walk-through of the Patient Exam Rooms on 03/03/2025 at 1:26 PM, the following observations were made: An observation in Patient Exam Room 1 evidenced a small trash can under the sink without a cabinet under it. An observation in Patient Exam Room 2 evidenced a small trash can under the sink without a cabinet under it. An observation in Patient Exam Room 5 evidenced		meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. ¿ General Cleanliness and Infection Control Guidelines. Emphasis will be placed on: ¿ Clean supplies may not be kept under dirty sinks. ¿ The facility will maintain a clean, safe, and aesthetically pleasant environment for patients, staff, and visitors. Effective 3/12/2025, the Home Therapy Program Manager will conduct three times per week audits, utilizing specific plan of correction audit tool for 2 weeks, and then weekly for 2 weeks, then monthly for an additional 2 months or until 100% compliance is achieved. With a focus on ensuring the facility maintains a clean, safe and aesthetically pleasant environment. The focus will also be on ensuring no clean supplies are kept under dirty sinks. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAPI calendar. Monitoring will be done through the specific plan of correction audit tool.	

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	a small trash can under the sink without a cabinet under it. An observation in Patient Exam Room 6 evidenced a small trash can, EZ Gel Drain clean bottle, and a black filing tote under the sink without a cabinet under it. 4. During an interview with the CM on 03/03/2025 at 4:15 PM, they indicated the sinks were supposed to have nothing under them.		The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Home Therapy Program Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring	

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			documentation, are available for review at the clinic. Completion Date: 04/03/2025.	
V 0143 Bldg. 00	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS Based on observations and interviews, the facility failed to ensure expired items and medications were removed from 6 of 6 Patient Exam Rooms and 1 of 1 medication room for a stand alone home dialysis program. Findings Include: 1. A review of a Fresenius Kidney Care policy dated 02/06/2023 titled "Medication Preparation and Administration" indicated but was not limited to, " ... Monitoring Expired Medications: Expiration dates for all stored medications are to be monitored on a monthly basis. Expired medications are to be discarded ..." 2. During a flash tour of the facility on 03/03/2025 evidenced, the following observations were made: An observation made in the Medication room evidenced 23 Tuberculosis syringes with an expiration date of 10/31/2024 and a 10 milliliter (ml) syringe with an expiration date of 11/30/2024 in the top drawer next to the sink. An observation made in Patient Exam Room 2 evidenced a 25 gauge (G) safety glide needle with an expiration date of 06/2020 and a 21 G safety glide needle with an expiration date of 10/2020 in the top drawer next to the sink. A single pair of exam gloves, with an expiration date of 05/01/2024, were in the cabinet above the sink.	V 0143	V143 On 3/13/2025, The Home Therapy Program Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. ¿ Medication preparation and administration. ¿ Expiration dates of Sterile supplies. Emphasis will be placed on: ¿ Expiration dates for all stored medications will be monitored on a monthly basis. o Expired medications will be discarded. ¿ Sterile items will be appropriately disposed of sterile items that have reached the expiration date. On 3/3/2025, all expired medications and supplies were removed. Effective 3/12/2025 the Home Therapy Program Manager will conduct three times per week audits, utilizing specific plan of correction audit tool for 2 weeks, and then	04/03/2025

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	An observation made in Patient Exam Room 3 evidenced a pair of exam gloves with an expiration date of 08/01/2021 in the drawer right next to the sink. A 23 G safety needle with an expiration date of 05/09/2021 and a 23 G safety needle with an expiration date of 02/08/2021 in the top middle drawer next to the sink. An observation made in Patient Exam Room 4 evidenced 2 pairs of sterile exam gloves with an expiration date of 03/2021, a 30 ml syringe with an expiration date of 09/30/2022, and 2 boxes from Entity 1 with an expiration date of 02/28/2025 in the cabinet above the sink. 3. An observation of Patient Exam Room 1 on 03/03/2025 at 10:40 AM evidenced a 25 G safety glide needle with an expiration date of 11/30/2021 in the drawer next to the sink. 4. An observation of the medication room on 03/03/2025 at 11:00 AM, the CM opened the locked medication cabinets, evidenced 20 vials of 50 milligram (mg) Venofer (a medication for iron deficiency) with an expiration date of 01/20/2025. During an interview with Registered Nurse 3 on 03/03/2025 at 11:10 AM, they indicated they were the ones to check expiration dates on the medications. They explained they only used the 100mg vials of Venofer, but should have seen them and disposed of them when they expired. 5. During an interview with the CM on 03/03/2025 at 10:45 AM, they indicated the expired items in the patient exam rooms 1- 5 and the medication room were inexcusable and there should not be so many expired items. 6. During a review of the clear three drawer organizer in Patient Exam Room 5 on		weekly for 2 weeks, then monthly for an additional 2 months or until 100% compliance is achieved. With a focus on ensuring expiration dates for all stored medications are monitored on a monthly basis and discarded if expired. The focus will also be on ensuring all sterile items are appropriately disposed of once the reach their expiration date. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAPI calendar. Monitoring will be done through the specific plan of correction audit tool. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Home Therapy Program Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all	

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	03/03/2025 at 10:03 AM, observed the following: 17 - A.V. Fistula (Arteriovenous Fistula, connection between an artery and vein used for dialysis) Needle Set 17 G x 1" had an expiration date of 12/30/2024, 5 - A.V. Fistula Needle Set 17 G x 1" had an expiration date of 06/30/2024, 3 - Button Hole Needle Settle with Anti-Stick Dull Bevel 15 G x 1.25" had an expiration date of 08/31/2021, 3 - A.V. Fistula Needle 15 G x 1" had an expiration date of 01/20/2025, 5 - Hemodialysis (medical treatment that removes waste products and excess fluid from the body when the kidneys are unable) Fistula Needle Set 15 G x 1" had an expiration date of 01/31/2025, 1 - Hemodialysis Fistula Needle Set 15 G x 1.25" had an expiration date of 01/31/2025, Review of the cabinet drawer in Patient Exam Room 5 observed the following: 23 - clear top vacutainer blood collection tubes had an expiration date of 10/31/2024. 7. During a review of the clear three drawer organizer in Patient Exam Room 6 on 03/04/2025 at 1:26 PM, observed the following: an open box with 24 remaining ChloraPrep One-Step had an expiration date of 01/2024. Review of the cabinet drawer in Patient Exam Room 6 observed the following: 8 - gold top vacutainer blood collection tubes had an expiration date of 01/31/2025. During an interview on 03/04/2025 at 4:06 PM, the CM indicated they would address the expired supplies found in Patient Exam Room 6.		identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/03/2025.	
V 0402 Bldg. 00	494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY			

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	Based on observation, record review, and interview, the facility failed to ensure the building was maintained to ensure the safety of patients and staff and boxes stored appropriately for 1 of 1 stand-alone home dialysis programs. Findings Include: 1. A review of a Fresenius Kidney Care policy dated 11/04/2024, titled "General Cleanliness and Infection Control Guidelines" indicated but was not limited to, "The purpose of this policy is to provide guidance for FKC staff on ... maintaining a clean, safe, and aesthetically pleasant environment for patients ... All areas must be kept clean and organized ..." 2. A review of a Fresenius Kidney Care policy dated 04/05/2021, titled "Storage of Supplies" indicated but was not limited to, " All clean or sterile supplies ... must be stored off the floor ..." 3. During a flash tour of the facility on 03/03/2025 at 9:40 AM, the following observations were made: An observation of the door used as the employee entrance evidenced a one inch crack where light shone through from the outside at the bottom of the door with a cool breeze. An observation of the door to the outside in the storage room, where the Peritoneal Dialysis (a thin catheter inserted into the abdomen to remove excess waste from the blood when the kidneys failed) supplies were kept, evidenced a cool breeze in the room and light from the outside from the small half inch opening along the bottom of the right door and a half inch opening in the middle at	V 0402	V402 On 3/13/2025, the Home Therapy Program Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. ¿ General Cleanliness and Infection Control Guidelines. ¿ Storage of Supplies. Emphasis will be placed on: ¿ The facility will maintain a clean, safe, and aesthetically pleasant environment for patients, staff, and visitors. ¿ All areas will be kept clean and organized, including but not limited to treatment areas, water/supply rooms and offices. Walkways must be kept clear of debris and free of clutter. ¿ All clean or sterile supplies, except drums of concentrate, will be stored off the floor. ¿ All supplies will be stored in a clean, well lit, and climate-controlled environment. ¿ Proper storage conditions are necessary to provide a safe environment and to ensure supplies are not expired, contaminated or damaged. By 3/26/2025, weather stripping will be added to the door to the outside in the storage room. The Biohazard Room and Peritoneal storage room was cleaned of any dust and debris and boxes were	04/03/2025

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	the bottom where the two doors connected. The floor in front of the door evidenced 59 wood chips of varying sizes, with the biggest at 2 inches long. An observation of the Biohazard room evidenced in the corner on the floor next to the door a clump, around six inches in diameter, of cobwebs, leaves, dirt, and dust. The dust and leaves followed along the border of the wall and the floor an inch in width to the back right corner. The floor in front of the door had a sign titled "Medical Waste" coated in dust. The floor next to the back wall evidenced a red cap with a diameter of three inches, leaves, dust, wood chips, and pieces of paper in a clump lining the back wall as long as a foot along the back wall. The room included four unmarked boxes on the floor. During an interview with the CM on 03/03/2025 at 10:45 AM, when queried regarding the doors, they indicated they needed to put a weather strip placed under the doors. When queried regarding the wood chips in front of the door to the outside of the Peritoneal Dialysis storage room and the dirty clumps in the biohazard room, they indicated they needed to clean the rooms. The CM indicated they would break down the boxes and get rid of them now.		removed. Effective 3/12/2025 the Home Therapy Program Manager will conduct three times per week audits, utilizing specific plan of correction audit tool for 2 weeks, and then weekly for 2 weeks, then monthly for an additional 2 months or until 100% compliance is achieved. With a focus on ensuring the facility will maintain a clean, safe, and aesthetically pleasant environment for patients, staff, and visitors. All areas will be kept clean and organized, including but not limited to treatment areas, water/supply rooms and offices. Walkways must be kept clear of debris and free of clutter. All clean or sterile supplies, except drums of concentrate, will be stored off the floor. And all supplies will be stored in a clean, well lit, and climate-controlled environment. Proper storage conditions are necessary to provide a safe environment and to ensure supplies are not expired, contaminated or damaged. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled	

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			audits based on the QAPI calendar. Monitoring will be done through the specific plan of correction audit tool. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Home Therapy Program Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is	

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			effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/03/2025.	
V 0520 Bldg. 00	494.80(d)(2) PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO Based on record review and interview, the facility failed to update the Plan of Care (POC) monthly for 1 of 1 active unstable patient. (Patient #1) Findings Include: 1. A Fresenius Kidney Care policy dated 07/03/2023 titled "Comprehensive Interdisciplinary (IDT) Assessment and Plan of Care" indicated but was not limited to, " ... Unstable patients must be reassessed by the IDT monthly. Monthly reassessment and any POC updates related to the reason the patient is considered "unstadble" must be documented ..." 2. Review of an undated facility document titled, "Patients listed as Unstable over the last 90 days" indicated but was not limited, " ... Patient #1 3/24/2025 HHD, unstable for not meeting adequacy" 3. A review of Patient #1's clinical record evidenced a POC with a meeting date of 11/11/2024, last patient status stable, and next POC meeting 11/11/2025. Patient #1's clinical record failed to evidence care	V 0520	V520 On 3/13/2025, Home Therapy Program Manager, held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. ¿ Comprehensive Interdisciplinary (IDT) Assessment and Plan of Care Emphasis will be placed on: ¿ Unstable patients will be reassessed by the IDT monthly. ¿ Monthly reassessment and any POC updated related to the reason the patient is considered "unstable" must be documented until the issues have been resolved or the IDT (including the patient if possible) determines that the condition is chronic. Effective 3/12/2025, the Home Therapy Program Manager will conduct bi-weekly audits utilizing specific plan of correction audit tool for 3 weeks, and then monthly for an	04/03/2025

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	plan meeting since 11/11/2024. Review of Patient #1's clinical record revealed a Provider note dated 01/21/2025 and signed by Other Physician 3. The note indicated but was not limited to, " ... Patient is not stable ... Comments: Unstable ..." Review of Patient #1's clinical record revealed a Provider note dated 02/24/2025 and signed by Other Physician 3. The note indicated but was not limited, " ... Patient is not stable ... Comments: Unstable, non-compliant with treatment ... does not like to sit down for multiple hours ..." Review of Patient #1's clinical record revealed a Psychosocial Progress note dated 02/24/2025 and signed by MSW 1. The note indicated but was not limited to, " ... Patient made unstable ..." During an interview on 03/03/2025 at 12:19 PM, the CM indicated Patient #1 had a POC meeting in December, and the facility was planning to make the patient unstable this month. During an interview on 03/04/2024 at 4:12 PM, RN 2 indicated POC meetings are monthly if a patient is deemed unstable. When queried what would classify a patient as unstable, RN 2 indicated if a patient has frequent hospitalizations or is noncompliant with treatment. During an interview on 03/04/2025 at 4:37 PM, the CM indicated POC meetings are completed monthly until the patient is deemed stable. When queried about the Provider note from 01/21/2025 indicating Patient #1 is unstable, the CM indicated Patient #1 should have been made unstable all of these months.		additional 3 months or until 100% compliance is achieved. With a focus on ensuring all unstable patients are reassessed by the IDT monthly in the comprehensive assessment and the Plan of Care will be updated monthly with any changes related to the reason the patient is considered unstable. This must be documented monthly until the issues have been resolved or the IDT (including the patient if possible) determines that the condition is chronic. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAPI calendar. Monitoring will be done through the specific plan of correction audit tool. The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Home Therapy Program Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAPI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152588	A. BUILDING 00 B. WING	03/04/2025

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
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			other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAPI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 4/03/2025.	