STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152582	A. BUILDING 00 B. WING	03/07/2025

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE SPENCER	11 CRANE AVE SPENCER, IN 47460

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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: 03/05/2025-03/07/2025 Active Census: 21 At this Emergency Preparedness survey, FMC Spencer was found not in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. QR by A4 on 03/17/2025	E 0000		
E 0039 Bldg. 00	403.748(d)(2), 416.54(d)(2), 418.113(d)(EP Testing Requirements Based on record review and interview, the facility failed to ensure all employees participated in a community-based or tabletop disaster exercise to test their emergency plan for 1 of 1 facility Emergency Preparedness review. Findings include: A 07/03/2023 policy titled "Guidelines for Emergency Preparedness" indicated that the facility staff must annually participate in a community-based disaster drill. The policy indicated that if staff cannot participate, they must document why they did not participate in a community-based drill. In addition to community-based drills, the staff should select an event of high likelihood and conduct a tabletop	E 0039	**E-039 EP TESTING REQUIREMENTS CFR(s): 494.62(d)(2)** On 03/07/2025, the Facility Administrator 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	04/06/2025

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

Andrew Bundy | Director of Operations | 03/30/2025

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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	exercise. A review of the Emergency Preparation program set forth in writing failed to evidence the facility participated in a community-based or tabletop exercise for 2023. During an interview on 03/06/2025 at 3:00 PM, the FA stated she could not find the 2023 tabletop or community-based exercise. She indicated that their computer system would delete all old information once they complete a new exercise. She stated the facility had a different FA at that time.		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 initially and annually. Review the FKC Facility Emergency Information Directory is complete and current. By 04/07/2025 Director of Operations will conduct a facility Table-Top Drill on Tornado 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 3/31/2025, the Facility Administrator will conduct monthly audits utilizing specific plan of correction audit tool for 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.	

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			The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly. The Facility Administrator 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	

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			minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/06/2025	
V 0000 Bldg. 00	This visit was for a CORE Federal Recertification survey of an ESRD provider. Survey Dates: 03/05/2025-03/07/2025 Census by Service Type: In-Center Hemodialysis: 21 Isolation: Waiver Abbreviations: CVC- Central Venous Catheter FA- Facility Administrator RN- Registered Nurse PCT- Patient Care Technician	V 0000		
V 0113 Bldg. 00	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Based on observation, record review, and interview, the facility staff failed to ensure they removed their gloves and performed hand hygiene after touching dirty equipment and bloodlines and before touching patients' items for 2 of 2 staff observed providing patient care. (RN 1, PCT 2)	V 0113	**V113 IC-WEAR GLOVES/HAND HYGIENE CFR(s): 494.30(a)(1)** On 03/07/2025, the Facility Administrator held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.	04/06/2025

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	Findings include: 1. An 11/06/2025 policy titled "Hand Hygiene" indicated that staff are to perform hand hygiene after contact with inanimate objects near the Patient. 2. During an observation on 03/05/2025 at 1:55 PM, RN 1 touched the dialysis machine with gloved hands, folded Patient 10's blanket, and placed it in the Patient's bag. During an interview on 03/07/2025 at 3:23 PM, RN 1 stated that staff should remove gloves and perform hand hygiene after removing bloodlines or touching the dialysis machine. RN 1 stated that staff should apply new gloves when touching the Patient's items, such as a blanket and wheelchair. 3. During an observation on 03/05/2025 at 3:39 PM, PCT 2 disconnected Patient #7's CVC bloodlines and typed on the dialysis machine with gloved hands. PCT 2 then folded Patient #7's blanket and placed it in the Patient's bag, assisted the Patient to the wheelchair, and pushed the Patient to the scale. PCT 2 failed to remove gloves and perform hand hygiene after touching bloodlines and the dialysis machine and before touching the Patient's blanket, bag, and wheelchair. 4. During an interview on 03/06/2025 at 2:50 PM, the Medical Director stated that staff members follow facility policy and should remove gloves and perform hand hygiene after touching bloodlines, the dialysis machine, and the Patient's belongings. 5. During an interview on 03/07/2025 at 8:45 AM, PCT 2 stated the Patient's belongings are		·Hand Hygiene Emphasis will be placed on: ·Hand hygiene includes either washing hands with soap and water or using a waterless alcohol-based antiseptic hand rub with 60-90% alcohol content when: ·Hands are visibly dirty or contaminated with proteinaceous material, blood, or other body fluids ·Before and after direct contact with patients ·Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medication ·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 Effective 03/07/2025 Facility Administrator will conduct 3 days per week audits, utilizing the facility specific audit tool for 2 weeks, with a focus on ensuring hand hygiene is done using soap and water or waterless	

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	considered dirty, and she would wear gloves when touching personal belongings.		alcohol-based antiseptic hand rub when hands are visibly dirty, before and after contact with patients, before performing any invasive procedure, immediately after removing gloves, after contact with body fluids, after contact with inanimate objects near patient and when moving from a contaminated body site to a clean body site of the same patient. The audits will then go to weekly for an additional 2 weeks 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 Facility Administrator 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.	

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			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: 04/06/2025.	
V 0122 Bldg. 00	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL Based on observation, record review, and interview, the facility failed to follow applicable infection control procedures when cleaning and disinfecting contaminated surfaces and equipment for 2 of 2 observations of cleaning and disinfecting the dialysis station. (Station 3, Station 8) Findings include: 1. A 09/05/2023 policy titled "Cleaning and Disinfecting the Dialysis Station" indicated staff	V 0122	**V122 IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL** On 03/07/2025, the Facility Administrator held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Cleaning and Disinfecting the Dialysis Station Emphasis will be placed on: Area including the dialysis	04/06/2025

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	are to disinfect the dialysis station, including the dialysis wall box and countertop located directly behind the treatment machine at the end of each treatment. 2. During an observation on 03/05/2025 at 3:12 PM, PCT 2 failed to disinfect the wall box and countertop directly behind the treatment chair at Station 3. 3. During an observation on 03/05/2025 at 8:45 AM, PCT 2 failed to disinfect the wall box and countertop directly behind the treatment chair at Station 8. 4. During an interview on 03/05/2025 at 2:23 PM, RN 1 stated staff should disinfect the wall box and countertop behind the dialysis machine at the end of each treatment. She stated that all staff receive education on disinfecting the stations and that they follow the policy. 5. During an interview on 03/07/2025 at 8:10 AM, PCT 2 stated staff should disinfect the wall box and countertop at the end of each treatment. She stated the wall box and countertop are part of the station.		machine, chair/bed and other reusable equipment or supplies utilized during dialysis treatment, patient training, and/or patient clinic visits. Dialysis Wall Box- A box designed to connect central distribution systems to a hemodialysis machine that is located in the chase wall behind the machine. Dialysis wall boxes and the area/wall around the wall box must be routinely cleaned at the end of each treatment day or immediately if splattered with blood. All surfaces shall be surface disinfected with 1:100 bleach solution. Special attention should be given to removing build-up and/or cleaning splatter and spray of concentrate solution. If concentrate leaks are noted at the wall box, staff should notify biomedical services for repair. Effective 06/28/2025 Facility Administrator will conduct 3 days per week audits, utilizing the facility specific audit tool, with focus on ensuring the wall boxes and countertop behind the machine in the patient station are disinfected with a 1:100 bleach solution after each patient treatment, for 2 weeks and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance.	

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			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 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 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	

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			of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/06/2025.	
V 0143 Bldg. 00	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS Based on observation, record review, and interview, the facility staff failed to ensure that one opened multiple-dose vial was initialed and dated for 1 of 1 in-center medication refrigerator observation and that two expired medication vials were discarded in 1 of 1 patient emergency cart observation. Findings include: 1. A 02/06/2023 policy titled "Medication Preparation and Administration" indicated that staff should place the date and initials on opened medication vials and that they should discard expired medications. 2. During a flash tour on 03/05/2025 at 9:35 AM, the surveyor found one opened Tubersol (medication used to aid in the diagnosis of Tuberculosis infection in persons at increased risk of developing the disease) multiple-dose vial in the medication refrigerator without a date. The staff failed to include the date and initials of the person who opened the medication vial in the medication refrigerator. During an interview on 03/05/2025 at 9:35 AM, RN 1 stated staff should mark the vial with a date,	V 0143	**V143 IC: ASEPTIC TECHNIQUES FOR IV MEDS CFR(S): 494.30(b)(2)** On 03/07/2025, the Facility Administrator held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Medication Preparation and Administration Storage of Supplies Emphasis will be placed on: Supplies must be rotated First in-First Out (FIFO) to ensure products maintain quality and do not expire. Appropriately dispose of items that have reached the expiration date. Expiration dates for all stored medications are to be monitored on a monthly basis. Expired medications are to be discarded via Fresenius Kidney Care off-site return program or in accordance with local and/or state law. When preparing	04/06/2025

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	time, and initial once the vial was open. 3. During a flash tour on 03/05/2025 at 9:59 AM, the surveyor found two Sodium Bicarb (medication used to treat metabolic acidosis, shock, and cardiac arrest) vials that expired 03/01/2025 in the patient emergency cart. The staff failed to discard the two expired medication vials. 4. During an interview on 03/05/2025 at 10:00 AM, the FA indicated staff should discard expired medications.		medications if the vial is not used immediately in its entirety, the nurse or PCT (if allowed by state regulations), must place the date and time the vial was opened on the medication label along with their initials. Note: To ensure all open vials are properly marked, the nurse must never walk away from an opened multi-dose vial without writing the date and time the vial was opened. Label any open multi-dose vial that is not used immediately and store vial accordingly. On 03/05/2025, Facility Administrator removed all expired medications from medication refrigerator and emergency cart. Effective 03/07/2025 Facility Administrator will conduct 3 days per week audits, for 2 weeks utilizing the facility specific audit tool, with focus on ensuring all medications are monitored monthly and properly disposed of when they reach their expiration, and if medication/multidose vial is not used in its entirety, immediately it will be date, timed and initialed the date it was opened, and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring	

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			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 Facility Administrator 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.	

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			The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/06/2025.	
V 0407 Bldg. 00	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Based on observation, record review, and interview, the staff failed to ensure patients' access sites, bloodline connections, and faces were able to be seen by staff for 2 of 9 patient observations. (Patients #13, #15) Findings Include: 1. A 05/01/2025 policy titled "Patient Assessment and Monitoring" indicated staff should ensure the patient's face was visible and uncovered. Staff must ensure patients' bloodline connections are secure and visible during treatment. 2. During an observation on 03/07/2025 at 8:50, Patient #13 access site and bloodlines were covered with a blanket while the Patients cap covered their face. PCT 2 approached the dialysis machine to type data. PCT 2 did not check the access site or bloodlines nor encourage the patient to remove the hat. 3. During an observation on 03/07/2025 at 8:50 AM, Patient #15 access site and bloodlines were covered with a blanket. At that time, PCT 1 approached Patient # 15's dialysis machine to type data. She did not check the access site or bloodlines or ask if she could look at the site. 4. During an interview on 03/07/2025 at 8:55 AM,	V 0407	**V407 PE-HD PTS IN VIEW DURING TREATMENTS CFR(s): 494.60(c)(4)** On 03/07/2025, the Facility Administrator held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Patient Assessment and Monitoring Emphasis will be placed on: Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. The following steps below should be for monitoring patient and machine parameters during treatment to include but not limited to: All patients must be under visual observation by clinical staff during treatment. Ensure each patient's face is visible and uncovered. Patients may not wear sunglasses or sleeping masks without medical documentation	04/06/2025

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	RN 1 stated she had spoken to Patients #13 and #15 about leaving the access sites and bloodlines uncovered during treatment, but both became defensive about it, so we let them go. 5. During an interview on 03/07/2025 at 9:00 AM, PCT 2 stated staff have educated Patient #13 and Patient #15 on having their access sites visible to staff during dialysis treatment. PCT 2 stated they become irritated when spoken to about it. 6. During an interview on 03/07/2025 at 9:15 AM, the FA stated the staff was to check the patient's access sites, bloodlines, and face to be visible even if staff educated the patient in the past.		confirming a photosensitivity condition. These products may obscure observation of patient's eyes. For patients' safety, staff must ask patients to lift or remove any medically justified eye covering during each 30-minute check in order to visually confirm alertness. Observe connections are secure and visible. If an external catheter is in use, observe and document that the HemaClip device is in place. Ensure access remains uncovered throughout the treatment Observe and ensure: Tape is secure Needles are intact No bleeding or infiltration is noted Effective 03/07/2025 Facility Administrator will conduct 3 days per week audits for 2 weeks utilizing the facility specific audit tool, with focus on ensuring machine and safety checks are completed every 30 minutes but not to exceed 45 minutes and patients faces and accesses and lines connections are visible and uncovered at all times, the audits will then go to weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring	

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	152582	A. BUILDING 00 B. WING	03/07/2025

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			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 Facility Administrator 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.	

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			The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic. Completion Date: 04/06/2025.	
V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P Based on observation, record review, and interview, the facility staff failed to ensure heparin syringe labels included a time and initials when preparing medication for 1 of 2 medication cabinet observations. (medication cabinet 1) Findings include: A 02/06/2023 policy titled "Medication Preparation and Administration" indicated that if staff prepares medication in a syringe, staff should label the syringe with the date, time, and initials of the person who prepared the medication if not used immediately. During a flash tour on 03/05/2025 at 9:35 AM, the surveyor found nine pre-drawn 10 ml (milligrams) of heparin (anticlotting medication) syringes and 12 pre-drawn 3 ml heparin syringes with labels identifying the name of the medication and date in medication cabinet 1. Staff failed to include the time and initials of the person who prepared the medication for all syringes in medication cabinet 1. During an interview on 03/05/2025 at 9:40 AM, PCT 1 stated she drew the heparin into the syringes and could not explain why she did not time and initial the attached labels. PCT 1 stated staff should draw the medication into the syringe	V 0715	**V715 MD RESP-ENSURE ALL ADHERE TO P&P CFR(s): 494.150(c)(2)(i)** On 03/07/2025, the Facility Administrator held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy. Medication Preparation and Administration Emphasis will be placed on: All medications in syringes not being administered immediately shall be labeled appropriately with the name of the medication, route, dose, name of patient, date, time and initials of the person who prepared the medication. If more than one syringe of the same medication is needed for a single patient, mark the label as “1 of 2, 2 of 2.” Effective 03/07/2025 Facility Administrator will conduct 3 days per week audits, for 2 weeks, utilizing the facility specific audit	04/06/2025

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	and place a label indicating the date, time, and initials of the person who prepared the syringes. During an interview on 03/06/2025 at 3:00 PM, the FA stated staff are to mark a time and their initials on the syringe once they draw mediation up into a syringe.		tool with focus on ensuring the. A focus will also be on ensuring all pre-drawn medications are properly labeled with the name of the medication, route, dose, name of patient, date, time and initials of the person who prepared the medication, the audits will then go to weekly for an additional 2 weeks 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 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 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	

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			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: 04/06/2025.	