STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	04/17/2025

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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 Dates: 04/15/2025, 04/16/2025, and 04/17/2025 Facility Number: 011063 CCN: 152562 Census: In Center Hemodialysis Patients: 72 QR: A 1 4/28/2025	E 0000		
E 0023 Bldg. 00	403.748(b)(5), 416.54(b)(4), 418.113(b)(Policies/Procedures for Medical Documentation Based on observtion, record review, and interview, the dialysis facility failed to evidence their emergency prepardness plan included a system of medical documentation that secures and maintains availability of patient records. Findings include: A revised policy, dated 07/03/2023, titled "Guidelines For Emergency Preparedness" indicated that patient emergency information and contact lists should be created and locked in the emergency supply boxes or cart. During an observation on 04/15/2025, beginning at 11:40AM, a review of the dialysis facility emergency preparedness "kit" failed to evidence a	E 0023	On May 5th, 2025, the Clinical Manager held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the policies: Guidelines for Emergency Preparedness Emergency and Disaster Responsibility Guidelines Emphasis will be placed on the Clinical Manager to maintain current listings of patients including local contact, emergency contact and evacuation contact information. The information will be reviewed and updated quarterly and placed in the secure evacuation box. By	05/16/2025

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Martha C. Rocha-Veloz	Clinic Manager	05/05/2025

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	current list of patients' demographics, dialysis prescription, and emergency contacts. During an interview on 04/15/2025, begining at 11:40AM, the Administrative Assistant [AA] indicated that patient information was located in an emergency binder, was not kept in or near the emergency preparedness kit, and was updated quarterly. The AA was unable to locate the binder. During an interview on 04/15/2025, beginning at 11:41AM, RN 1 indicated that she was unsure where patient information for the emergency preparedness kit should be located or how often it should or was updated.		May 7, 2025, the Emergency and Disaster Patient Contact Information Sheets will be placed in the Emergency evacuation box. Effective May 7th, 2025, the Clinical Manager will conduct monthly audits with a focus on ensuring the Emergency Preparedness information 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 monthly QAPI Committee meeting. The Clinical Manager is responsible for reviewing, analyzing and trending 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 for presenting 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 for providing oversight, reviewing	

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			findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAPI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.	
V 0000 Bldg. 00	This visit was for a CORE Federal recertification survey of an ESRD provider. Survey dates: 04/15/2025, 04/16/2025, and 04/17/2025 Census by Service Type: In Center Hemodialysis: 72 Total Census: 72 Isolation Room: No isolation room Isolation waiver: No The abbreviations used in this survey report: RN for Registered Nurse and PCT for Patient Care	V 0000		

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	Technician QR: A1 4/28/2025			
V 0111 Bldg. 00	494.30 IC-SANITARY ENVIRONMENT Based on observation, record review, and interview, the dialysis facility failed to ensure bleach water solution, minimize transmission of infectious agents, was covered with a lid when not in use, to reduce loss of efficacy, in 1 of 2 observations on the dialysis treatment floor. Findings include: 1. A revised policy, dated 02/03/2025, titled "Mixing Bleach" indicated that Bleach solutions must be made daily, labeled, and covered by a lid to prevent contamination. 2. During an observation period on 04/16/2025, from 2:40 PM-3:45 PM, a container of 1:100 bleach solution was left uncovered, with the lid on the counter beside the container, during the duration of the observation period 2:40 PM- 3:45 PM. 4. During an interview on 04/17/2025, beginning at 4:30 PM, RN3 indicated that bleach solutions on the treatment floor should be covered with a lid when not in use.	V 0111	On May 5,2025 the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·Mixing Bleach Emphasis was placed on the facility staff to ensure the bleach solution is in an opaque container and the lid is present and on correctly when not in use. Effective 5/7/25, the Clinical Manager will conduct weekly audits with a focus on ensuring staff are placing the lid on the bleach container when not in use utilizing the infection control audit tool for 4 weeks or until 90% 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 QAI Committee meeting monthly. The Clinical Manager is	05/16/2025

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			responsible for reviewing, analyzing and trending 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 for presenting the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. POC Completion 5/16/25.	
V 0128 Bldg. 00	494.30(a)(1)(i) IC-HBV-ISOLATION (EXISTING FACILITY) Based on record review and interview, the dialysis	V 0128	On May 5,2025 the Clinical Manager held a staff meeting and	05/16/2025

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	facility failed to have available an isolation room or a waiver of the requirement for an isolation for the treatment of HB's Ag positive patients. Findings Include: 1. The Provider was initially built and certified prior to October 14, 2008. During a record review of the dialysis facility waivers and agreements, the Provider failed to evidence a CMS waiver of the requirement for an isolation room or area. 2. During an interview on 04/17/2025, beginning at 9:30AM, the Corporate Senior Regulatory Manager indicated that while the dialysis facility has agreements from other facilities to accommodate isolation needs, the dialysis facility does not have a CMS waiver for the requirement of an isolation room or area.		reinforced the expectations and responsibilities of the facility staff on policies: ·Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+) Emphasis was placed on obtaining a CMS waiver. Paperwork was submitted to the Deputy Director/Oasis Coordinator at the Indiana Department of Health on April 17, 2025. Facility was built and certified prior to October 14, 2008. Facility has a transfer agreement in place with a local chronic facility that is less than 4 miles away. Effective 5/7/25, the Clinical Manager will conduct a monthly audit with a focus ensuring the facility maintains a Hepatitis B Antigen Positive Transfer Agreement with a local chronic facility, as required, and obtains a CMS waiver 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 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	

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			at the QAI Committee meeting monthly. The Clinical Manager is responsible for reviewing, analyzing and trending 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 for presenting the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. POC Completion 5/16/25.	
V 0143	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS			

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Bldg. 00	Based on observation, record review, and interview, the dialysis facility failed to ensure RN2 demonstrated aseptic techniques when dispensing and administering intravenous medications from vials in 1 of 2 observations of parenteral medication preparation and administration. Findings include: 1. A revised policy, dated 02/06/2025, titled, "Medication preparation and administration" indicated aseptic technique was to be used to prepare medications. The policy indicated medication vials were to be disinfected with an alcohol pad before each entry by a needle. 2. During an observation on 04/16/2025, beginning at 3:16PM, RN2 performed hand hygiene, removed protective top from medication vial, and failed to wipe the vial stopper with alcohol or any other disinfectant prior to withdrawing medication. 3. During an interview on 04/17/2025, beginning at 4:30PM, RN3 indicated that all medication vials should be disinfected with alcohol prior to withdrawing medication with a syringe.	V 0143	On May 5,2025 the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: Medication Preparation and Administration Procedure Emphasis was placed on facility staff to ensure disinfection of the medication vial with an alcohol pad each time before it is punctured with a needle. Effective 5/7/25, Clinical Manager will conduct weekly audits with a focus on following policy and procedure as it relates to medication vial disinfection utilizing infection control audit tool for 4 weeks or until 90% 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 QAI Committee meeting monthly. The Clinical Manager is responsible for reviewing, analyzing and trending 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	05/16/2025

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			responsible for presenting the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 5/16/25.	
V 0544 Bldg. 00	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Based on record review and interview, the dialysis facility failed to ensure PCT3 , PCT4, PCT5, and PCT6 administered the correct hemodialysis [HD] (a process to clean the blood of a patient whose kidneys do not work normally) prescription in 5 of 8 in center hemodialysis clinical record reviews. Findings include:	V 0544	On May 5,2025 the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·Patient Assessment and Monitoring ·Pre-Treatment Safety Checks	05/16/2025

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	1. A revised policy, dated 02/06/2023 and titled "Pre-Treatment Safety Checks Procedure" indicated the clinician, initiating treatment, must verify the prescribed setup matches the patient. 2. A Treatment Flowsheet, dated 03/25/2025, for Patient #1 indicated the prescribed blood flow rate [BFR] was 400. PCT 4 charted a BFR of 450 at 7:08 AM, 7:38 AM, 8:07 AM, 8:32 AM, 9:02 AM, 9:40 AM, 10:06 AM, 10:36 AM, and 11:01 AM. 3. A Treatment Flowsheet, dated 04/01/2025, for Patient #2 indicated the prescribed BFR is 425. PCT 3 charted a BFR of 435 at 7:30 AM, 8:01 AM, 8:31 AM, 9:06 AM, 9:34 AM, and 10:08 AM. 4. A Treatment Flowsheet, dated 03/24/2025, for Patient #7 indicated the prescribed BFR is 415. PCT 5 charted a BFR of 450 at 3:01 AM, 3:35 PM, 4:04 PM, 4:33 PM, 5:01 PM, 5:31 PM, 6:06 PM, 6:35 PM, 7:03 PM, 7:32 PM, and 7:44 PM. 5. A Treatment Flowsheet, dated 04/16/2025, for Patient #19 indicated the prescribed BFR is 400. PCT 4 charted a BFR of 425 at 11:20 AM, 11:33 AM, 12:01 PM, 12:37 PM, 1:02 PM, 1:31 PM, 2:01 PM, 2:36 PM, 3:00 PM, and 3:30 PM. 6. A Treatment Flowsheet, dated 03/25/2025, for Patient #6 indicated the prescribed dialysis flow rate [DFR] is 800. PCT 6 charted a DFR of 500 at 9:32 AM, 10:08 AM, 10:32 AM, 11:01 AM, 11:33 AM, and 12:05 AM. 7. During an interview on 4/16/2025, beginning at 2:48 PM, RN 2 indicated that the RN may change the BFR higher to see how well a patient will tolerate it. 8. During an interview on 04/17/2025, beginning at		Procedure Emphasis was placed on: ·Emphasis will be placed on ensuring the facility staff follow the prescribed blood flow and dialysate flow rate so that adequate dialysis is achieved. Monitoring during treatment-Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. Check machine settings and measurements, check prescribed blood flow rate setting is correct, and the prescribed dialysate flow is being delivered. Document any findings and interventions in the medical record, including contact with the physician. Effective 5/7/25, the Clinical Manager will conduct weekly treatment sheet audits utilizing the medical record audit tool to ensure the prescription is followed or documentation is present for 4 weeks. Once 90% compliance is achieved monitoring will be done through the clinic audit checklist per QAI calendar. The Governing Body will determine on-going frequency of the audits based on compliance. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly.	

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	11:15 AM, The Medical Director indicated that RN's do not have autonomy, nor is there a protocol, to increase a BFR without an order. 9. During an interview on 04/17/2025, beginning at 4:30 PM, RN3 indicated that occasionally, BFR's may need to be decreased due to increased arterial pressure, but there would never be any reason that the BFR would be run higher than prescribed without a new order from MD.		The Clinical Manager is responsible for reviewing, analyzing and trending 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 for presenting the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 5/16/25	
V 0550 Bldg. 00	494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS	V 0550	On May 5,2025 the Clinical	05/16/2025

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	Based on observation, record review, and interview, the dialysis facility failed to ensure appropriate vascular access care when PCT2 cleaned the arteriovenous fistula [AVF] (entry into the blood vessel for hemodialysis [HD])(a process to clean the blood of a patient whose kidneys do not work normally), then repalpated area prior to cannulation (needle insertion) in 2 of 2 AVF cannulations observed. Findings include: 1. A revised policy, dated 04/19/2024, titled "Assessment and Cannulation of AVF/AVG for Inpatient Setting" indicates that the needle insertion site should be disinfected, allowed to dry, and to not touch cannulations sites after skin disinfection. 2. During an observation on 04/15/2025, beginning at 11:05 AM, at Station #5, PCT2 disinfected the cannulation site of Patient 13, allowed it to dry, and then palpated the cannulation site and inserted the needle. 3. During an observation on 04/15/2025, beginning at 11:46 AM, at Station #6, PCT2 disinfected the cannulation site of Patient 14, allowed it to dry, and then palpated the cannulation site and inserted the needle. 4. During an interview on 04/17/2025, beginning at 4:30 PM, RN3 indicated that after disinfecting the cannulation site, needle insertion site should not be touched, and if repalpation is needed, then area should be cleansed again prior to needle insertion.		Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: Access Assessment and Cannulation Emphasis was placed on: ·Emphasis will be placed on facility staff to ensure skin antisepsis is completed prior to cannulation and completed again if access site is touched after initial antisepsis. ·Skin antisepsis: Prior to treatment, ask patient to wash access area with soap per hand hygiene procedure. Wash access if patient is unable to clean their access. 70 % isopropyl alcohol pad: Using gentle friction, clean the access site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds. Perform skin antisepsis on one site at a time, allow it to dry, and then cannulate. Do not touch cannulation sites after skin disinfection. If the site is touched, skin antisepsis will be performed again. Effective 5/7/25 Clinical Manager will conduct weekly audits utilizing the infection control audit tool to ensure antisepsis is completed per policy for 4 weeks. Once 90% compliance is achieved monitoring will be done through the clinic audit checklist per QAI calendar. The Governing Body will determine	

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			on-going frequency of the audits based on compliance. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible for reviewing, analyzing and trending 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 for presenting the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.	

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	152562	A. BUILDING 00 B. WING	04/17/2025

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(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
V 0726 Bldg. 00	494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE Based on record review and interview, the dialysis facility failed to maintain accurate records in 1 of 2 record reviews of in-center hemodialysis [HD] (a process to filter the blood of a patient whose kidneys do not work normally) who have central venous catheters [CVC] (catheter into a large vein). Findings include: 1. A Hospital Discharge Summary, dated 03/11/2025, for Patient #4, indicated that Patient #4 had been admitted for a HD catheter infection and had placement of a new CVC on 03/05/2025. 2. During a clinical record review on 04/17/2025, for Patient #4 the following documents indicated that Patient #4's current dialysis access was a CVC catheter with an insertion date of 08/13/2019: A. A Treatment Run Sheet, dated 04/14/2025. B. A Treatment Run Sheet, dated 04/11/2025 C. A Treatment Run Sheet, dated 04/09/2025 D. A Treatment Run Sheet, dated 04/07/2025 E. A Treatment Run Sheet, dated 04/04/2025 F. A Treatment Run Sheet, dated 04/02/2025 G. A Treatment Run Sheet, dated 03/31/2025 H. A Treatment Run Sheet, dated 03/28/2025 I. A Treatment Run Sheet, dated 03/26/2025 J. A Treatment Run Sheet, dated 03/24/2025 K. A Basic Provider Note, dated 04/14/2025 L. A Comprehensive Provider Note, dated 04/02/2025	V 0726	Completion 5/16/25. On May 5,2025 the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: Medical Record Documentation Standards Emphasis was placed on: ·Emphasis will be placed on ensuring the facility staff maintain accurate patient records. The patient medical record will reflect the condition of the patient from the time of the first dialysis treatment until the patient is discharged. ·Document all facts and pertinent information related to an event, course of treatment, patient's condition, response to care and any deviation from and reason for deviation of standard treatment. Effective 5/7/25, the Clinical Manager will conduct an audit of 100% of patient medical records to ensure that each patient's current access is indicated in the medical record utilizing the medical record audit tool to ensure the prescription is followed or documentation is present for 4 weeks. Once 90% compliance is	05/16/2025

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	3. During an interview on 04/17/2025, the Clinical Manger indicated that staff was aware that the CVC dated 08/13/2019 had been removed and a new CVC had been placed.		achieved monitoring will be done through the clinic audit checklist per QAI calendar. The Governing Body will determine on-going frequency of the audits based on compliance. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible for reviewing, analyzing and trending 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 for presenting the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.	

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			The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 5/16/25	