STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152641	A. BUILDING 00 B. WING	08/09/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE SCOTT COUNTY	130 N WESTAVIA BLVD SCOTTSBURG, IN 47170

(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 Department of Health in accordance with 42 CFR 494.62. Survey Dates: 08/07/2024 - 08/09/2024 Active Census: 45 At this Emergency Preparedness survey, Fresenius Medical Care of Scott County was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. QR Completed on 08/15/2024 by A4	E 0000		
V 0000 Bldg. 00	This visit was for a CORE Federal recertification survey of an ESRD provider. Survey dates: 08/07/2024 - 08/09/2024 Census by Service Type: In-Center Hemodialysis: 45 Total Active Census: 45 Isolation Room: 1	V 0000		
V 0147 Bldg. 00	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Paula Rhoten	Director of Operations	08/20/2024

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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	Based on observation, record review, and interview the facility failed to ensure infection control guidelines were followed for exit site care when initiating a Central Venous Catheter (CVC) at the start of treatment for 1 of 2 CVCs observed (Patient #4). Findings include: 1. A policy titled "Changing the Catheter Dressing Procedure" indicated but was not limited to: "Cleaning the Site: Follow the steps below to clean the catheter exit site ...Remove swab stick from package ...2% Chlorhexidine and 70% alcohol ...clean the exit site beginning in the center and continuing outward the area of the size of the dressing to be applied in a concentric circle for 30 seconds and allow to dry a minimum of 30 seconds ..." 2. During an observation on 08/07/2024 at 11:20 AM, Patient Care Technician (PCT) 3 removed the old dressing from Patient #4's CVC, removed gloves, completed hand hygiene, and donned new gloves. The exit site was cleansed with 2% Chlorhexidine (topical antiseptic) for 10 seconds before applying a new dressing. PCT 3 failed to cleanse the CVC exit site for 30 seconds. 3. During an interview on 08/07/2024 at 11:36 AM, PCT 3 indicated that CVC exit sites should be cleansed for 30 seconds when using 2% Chlorhexidine and that she was not counting as she normally does when performing this task. PCT 3 denied using a clock/watch to ensure adequate	V 0147	On 8/16/2024, the Clinical Manager met with direct patient care staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policy: -Changing the Catheter Dressing Emphasis will be placed on: Cleaning the catheter exit site with 2% Chlorhexidine and 70% alcohol: -Ensure staff use gentle back and forth friction, clean the exit site beginning in the center and continuing outward the area of the size of the dressing to be applied (2 inches) in a concentric circle for 30 seconds and allow to dry a minimum of 30 seconds. Ensure all direct patient care staff are knowledgeable on cleaning the catheter exit site procedure steps -Ensure staff use a clock/watch to ensure sufficient cleaning time of 30 seconds for adequate exit site care. To monitor staff compliance with cleaning the exit site, beginning 8/26/2024, the Clinic Manager or designee will conduct observational infection control audits of staff changing the catheter dressing and cleaning the exit site daily x 2 weeks. Once compliance is achieved, the	09/20/2024

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	CVC exit site care was completed for Patient #4. 4. During an interview on 08/07/2024 at 12:32 PM, the Clinic Manager indicated the time frame for cleansing a CVC Exit Site using 2% Chlorhexidine was one minute and further indicated she would look up the policy to verify this. At 1:43 PM the Clinic Manager indicated that after review of the policy the CVC Exit Site should be cleansed for 30 seconds with 2% Chlorhexidine. 5. During an interview on 08/09/2024 at 10:05 AM, Registered Nurse (RN) 1 indicated the time frame for cleansing a CVC Exit Site using 2% Chlorhexidine was 30 seconds. 6. During an interview on 08/09/2024 at 10:23 AM, PCT 1 indicated the time frame for cleansing a CVC Exit Site using 2% Chlorhexidine was 30 seconds.		facility will decrease audit frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled audits based on the Quality Assessment and Performance Improvement (QAPI) calendar using the QAPI Clinic Audit Checklist Tools. Monitoring for this citation will be done using the Plan of Correction Audit Tool developed for this survey. It is the expectation of the Governing Body that 100% compliance is achieved. The Governing Body determined that the facility threshold be 90%. If the audit findings for cleaning the catheter exit site fall below 90%, the Governing Body will reconvene to determine revision and implementation of the revised action plan. The Medical Director will review the results of audits each month at the QAPI Committee meeting. 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	

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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.	
V 0455 Bldg. 00	494.70(a)(4) PR-PRIVACY & CONFIDENTIALITY-RECORDS Based on observation, record review, and interview the facility failed to ensure that privacy and confidentiality in personal medical records was maintained for 1 of 1 facility reviewed. Findings include: 1. A policy titled "Patient Rights and Responsibilities" indicated but was not limited to: "The patient has the right to ...Privacy and confidentiality in all aspects of treatment; Privacy and confidentiality in personal medical records ..."	V 0455	On 8/16/2024, the Clinical Manager met with facility staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policy: -Patient Rights and Responsibilities Emphasis will be placed on: -Direct patient care will ensure patient privacy and confidentiality in all aspects of treatment and in	09/20/2024

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	2. During an observation on 08/07/2024 at 10:20 AM, a clipboard containing patients' names, was lying uncovered on the ledge surrounding the nurses' station in the treatment center. Additionally, bags labeled with patient names and containing lab supplies on the ledge surrounding the nurses' station and at the clean sink/lab area in the treatment center. Patient information was visible to individuals walking by these areas. 3. During an interview on 08/07/2024 at 3:50 PM, Registered Nurse (RN) 1 indicated the patient names on the clipboard are at the nurses' station and it's not like patients are hanging out at the nurses' station; she indicated staff walks patients from the scale to their dialysis station for treatment. She indicated the names on the clipboard and the names on the lab bags could be a HIPAA (Health Insurance Portability and Accountability Act) violation and there could be a better process for protecting patients' information from being viewed by others. 4. During an interview on 08/07/2024 at 4:05 PM, the Administrator indicated patient names on the clipboard on the ledge at the nurses' station and the names on the lab bags in the treatment center should not be visible in order to protect patients' privacy.		personal medical records and information -Ensure patient specific information, i.e., patient names are not visible to other patients and visitors in the treatment area, including, but not limited to, ledges at the nurses station and lab supply bags, etc. To monitor staff compliance with protection of patient privacy and confidentiality in all aspects of treatment and personal medical records, beginning 8/26/2024, the Clinic Manager or designee will conduct observational audits of the treatment floor to assess for visibility of patient names and/or patient specific information daily x 2 weeks. Once compliance is achieved, the facility will decrease audit frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled audits based on the Quality Assessment and Performance Improvement (QAPI) calendar. Monitoring for this citation will be done using the Plan of Correction Audit Tool developed for this survey. It is the expectation of the Governing Body that 100% compliance is achieved. If the audit findings for patient privacy and confidentiality fall below	

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			100%, the Governing Body will reconvene to determine revision and implementation of the revised action plan. The Medical Director will review the results of audits each month at the QAPI Committee meeting. 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 of the issues. The QAPI and Governing Body minutes, education and monitoring	

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			documentation, are available for review at the clinic.	
V 0504 Bldg. 00	494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS Based on record review and interview the agency failed to ensure patient monitoring for blood pressure and pulse, during dialysis were completed every 30-45 minutes per policy for 3 of 5 patient records reviewed, (Patient #1, #4, #5) and that a pulse below 60 bpm (beats per minute) was verified manually and reported to the nurse in 1 of 5 patient records reviewed (Patient #4). Findings Include: 1. A policy titled "Patient Assessment and Monitoring" indicated but was not limited to: "During Treatment: Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes ...Follow the steps below for monitoring patient and machine parameters during treatment: Pulse: record pulse. Verify pulses manually if automated readings display below 60 or greater than 100 beats per minute. Report to the nurse patients whose heart rates have dropped below 60, risen above 100 or become irregular ...Ensure vital signs and overall condition are stable for discharge ..." 2. A document titled, "Patient Transfer: Care Transitions Report" for Patient #4 indicated but was not limited to: "Special Attentions: Okay to dialyze with systolic B/P [blood pressure] 80-180, diastolic B/P 40-95, and pulse 40-120 every tx [treatment] if non-symptomatic." 3. A treatment sheet dated 08/02/2024 for Patient #1 indicated a blood pressure/pulse assessment	V 0504	On 8/16/2024, the Clinical Manager met with direct patient care staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policy: -Patient Assessment and Monitoring Emphasis will be placed on: -Ensure staff obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations. - Ensure staff document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. To monitor staff compliance with patient monitoring every 30 minutes, not to exceed 45 minutes, beginning 8/26/2024, the Clinic Manager or designated Registered Nurse will review 25% treatment sheets daily x 2 weeks. Once compliance is achieved, the facility will decrease treatment	09/20/2024

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	documented at 2:03 PM with the next blood pressure/pulse assessment documented at 4:02 PM, 1 hour and 59 minutes later. 4. A treatment sheet dated 07/24/2024 for Patient #4 indicated a pulse rate of 63-66 bpm throughout the 4 hour treatment until the last 30 minutes. A pulse rate of 36 was obtained by Patient Care Technician (PCT) 2 at 2:31 PM with an additional pulse rate of 31 at 2:57 PM. No further pulse assessment was documented on this day. Patient #4 was discharged home. PCT failed to notify the Registered Nurse (RN) of the pulse rates. 5. A treatment sheet dated 07/31/2024 for Patient #4 indicated a blood pressure/pulse assessment documented at 2:02 PM with the next blood pressure/pulse assessment documented at 3:02 PM, one hour later. 6. A treatment sheet dated 08/05/2024 for Patient #4 indicated a blood pressure/pulse assessment documented at 2:01 PM with the next blood pressure/pulse assessment documented at 3:02 PM, one hour later. 7. A treatment sheet dated 07/31/2024 for Patient #5 indicated a blood pressure/pulse assessment documented at 2:03 PM with the next blood pressure/pulse assessment documented at 3:01 PM, 58 minutes later. 8. During an interview on 08/08/2024 at 9:24 AM the Clinic Manager indicated it is the expectation that clinical staff document on patients during dialysis treatments every 30 minutes. This is to include, blood pressure, pulse, respirations, blood flow rates, dialysate flow rates, on-line clearance monitoring, venous & arterial pressures, and fluid removed. The Clinic Manager indicated that		sheet audit frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled monthly medical record audits based on the Quality Assessment and Performance Improvement (QAPI) calendar utilizing the QAPI Clinic Checklist Audit Tool. Monitoring for this citation will be done using the Plan of Correction Treatment Sheet Audit Tool developed for this survey. It is the expectation of the Governing Body that 100% compliance is achieved. The Governing Body determined that the facility threshold be 90%. If the audit findings for patient monitoring fall below 90%, the Governing Body will reconvene to determine revision and implementation of the revised action plan. The Medical Director will review the results of audits each month at the QAPI Committee meeting. 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	

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	sometimes the blood pressure/pulse rates won't show on the treatment sheets if clinical staff document within 30 seconds of dialysis machine alarming for next patient assessment. No further documentation was found in the Electronic Medical Record System per the Clinic Manager. 9. During an interview on 08/09/2024 at 10:05 AM, RN 1 indicated patient assessment, including blood pressure and pulse are to be documented every 30 minutes. If an abnormal finding is documented, such as a pulse outside of policy parameters, the PCT is not notify the RN. The RN completes an assessment and notifies the physician. 10. During an interview on 08/09/2024 at 10:23 AM, PCT 1 indicated that blood pressure/pulse assessments are documented every 30 minutes. If outside the normal range, the RN is notified.		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.	
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 failed to follow policy regarding securement of medications and labeling pre-drawn medications for 1 of 1 facility reviewed and failed to ensure the Registered Nurse (RN) assessment was completed prior to the start of dialysis treatment for 1 of 1 New Admission patient records reviewed (Patient #4). Findings include:	V 0715	On 8/16/2024, the Clinical Manager met with direct patient care staff to provide reeducation, elicit input, and reinforce the expectations and responsibilities of the facility staff on the following FKC Policies: -Medication Preparation and Administration -Comprehensive Interdisciplinary Assessment and Plan of Care	09/20/2024

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	1. A policy titled "Medication Preparation and Administration" indicated but was not limited to: "Pre-drawing Medications: Medications may be pre-drawn up to 4 hours prior to administration ...These pre-drawn medications shall be labeled and must be kept under the preparer's control or in a locked designated medication storage area or refrigerated, if necessary until delivery to the appropriate patient for administration ...Securement: The following steps must be taken for the securement: All medications will be kept in a locked cabinet except when in use ..." 2. A policy titled "Comprehensive Interdisciplinary Assessment and Plan of Care" indicated but was not limited to: "Patients changing modality are classified as new patients ...A registered nurse must perform an assessment on patients new to dialysis before initiation of their first treatment to determine immediate needs ..." 3. During an observation on 08/07/2024 at 9:48 AM, six pre-drawn syringes of Heparin, (a medication used to prevent clotting during dialysis) were found in an unlocked drawer in the medication preparation area. Three labeled syringes of Heparin for Patient #5 included the following doses: 2000 units, 6000 units, and 2200 units. Three additional syringes of Heparin for Patient #4 included the following doses: 1900 units, 7000 units, and 1900 units. The labels for all 6 pre-drawn syringes failed to include the time the medication was drawn up and the staff members initials. One opened vial of Heparin was found unsecured on the medication preparation area counter. 4. During an observation on 08/07/2024 at 12:32 PM while interviewing the Clinic Manager, two vials of opened Heparin were found unsecured on		Emphasis will be placed on: -Medication Preparation and Administration Ensure medications in syringes not being administered immediately are labeled appropriately with the name of the medication, route, dose, name of patient, date, time and initials of the person who prepared the medication. Ensure 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.” Ensure pre-drawn medications are labeled and kept under the preparer’s control or in a locked designated medication storage area or refrigerated, if necessary, until delivery to the appropriate patient for administration. In addition to the education provided, on 8/7/2024, the Clinical Manager removed and secured the three vials of Heparin found unsecured on the medication preparation counter during the survey. -Comprehensive Interdisciplinary Assessment and Plan of Care -Prior to Initiation of the Patients First Treatment for Patients New to Dialysis: Ensure a registered nurse (RN) performs an assessment on patients NEW to dialysis BEFORE initiation of their	

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	the medication preparation area counter. 5. A record review for a new admission, Patient #4, indicated an admission date of 06/07/2024. The initial treatment on 06/07/2024 was completed at 11:28 AM. The initial treatment started at 11:05 AM. The facility failed to ensure the initial assessment was completed prior to the start of treatment for Patient #4. 6. During an interview on 08/07/2024 at 10:15 AM, Registered Nurse (RN) 1 indicated that all pre-drawn medications are to be labeled with the name of the patient, medication name, dose, date, and time. The staff member responsible for drawing up the medication should initial the medication label and ensure securement in a locked drawer. 7. During an interview on 08/07/2024 at 12:32 PM, the Clinic Manager indicated that pre-drawn medications should be labeled and include the patient name, name of the medication, dose, date, and time. The staff member preparing the medication should initial the label and ensure securement in a locked drawer. 8. During an interview on 08/09/2024 at 10:05 AM, Patient Care Technician (PCT) 1 indicated that pre-drawn medications should include a label with the following information; patient name, medication name, dose, date, time, and initials of staff member preparing the medication. All medications should be secured in a locked cabinet or drawer until use. 9. During an interview on 08/08/2024 at 2:35 PM, the Clinic Manager indicated that the initial assessment is to be completed prior to the start of the first dialysis treatment and indicated that there		first treatment to determine immediate needs. The RN must document the assessment on the CIA in eCC, evaluation cascade in Chairside or multidisciplinary notes. Ensure that patients changing modality are classified as new patients and have comprehensive interdisciplinary assessments and plans of care completed with the same frequency as patients new to dialysis. On 8/16/2024, the Director of Operations reviewed the Statement of Deficiencies and on 8/19/2024 reviewed the developed Plan of Correction with the Medical Director. To monitor staff compliance with appropriate labeling of pre-drawn medications and securement of medications, beginning 8/26/2024, the Clinic Manager or designee will conduct observational medication preparation and proper medication securement audits utilizing the Plan of Correction Observational Audit Tool developed for this survey. Once compliance is achieved, the facility will decrease frequency to weekly x 2 weeks. Once compliance is sustained, the facility will resume regularly scheduled monthly medication audits based on the Quality	

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	is a "hard-stop" that will not allow treatment to begin prior to the nurse completing the assessment. The assessment is completed within the Electronic Medical Record, no paper charting of assessments are completed. The Clinic Manager indicated that Patient #4 was a transfer from another clinic, a home modality, and this could be the reason the initial assessment is documented later than the treatment start time. 10. During an interview on 08/09/2024 at 1005 AM, RN 1 indicated that assessments for all new admissions are completed prior to the start of their initial treatment. The initial assessment is completed in Chairside, the electronic treatment documentation system.		Assessment and Performance Improvement (QAPI) calendar utilizing the QAPI Clinic Audit Checklist Tools. To monitor registered nurse compliance with completion of an assessment on all patients new to dialysis prior to initiation of the first dialysis treatment, inclusive of patients changing modality, beginning 8/26/2024 the Clinical Manager or designated Registered Nurse will be responsible to review the medical record for all new patients, including patients changing modality for appropriate completion and documentation of the registered nurse assessment prior to initiation of the patients first dialysis treatment utilizing the Plan of Correction Audit Tool developed for this survey weekly x4 weeks. Once compliance is achieved and sustained, the facility will resume regularly scheduled medical record audits based on the QAPI calendar utilizing the QAPI Clinic Audit Checklist Tools. It is the expectation of the Governing Body that 100% compliance is achieved. The Governing Body determined that the facility threshold be 90%. If the audit findings for appropriate labeling of pre-drawn medications, securement of medications and registered nurse completion and	

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	152641	A. BUILDING 00 B. WING	08/09/2024

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			documentation of an assessment for all new patients prior to the patients first treatment fall below 90%, the Governing Body will reconvene to determine revision and implementation of the revised action plan. The Medical Director will review the results of audits each month at the QAPI Committee meeting. 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 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	

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			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.	