

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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: November 25th, 26th, 27th and December 2nd, 3rd, and 4th of 2024 Active Census: 72 Incenter Hemodialysis: 41 Home Peritoneal Dialysis: 24 Home Hemodialysis: 7 At this Emergency Preparedness survey, Fresenius Medical Care Noblesville was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. QR completed on 12/13/2024 AREA 4			E 0000			
V 0000 Bldg. 00	This visit was for a CORE Federal recertification. Survey Dates: November 25th, 26th, 27th and December 2nd, 3rd, and 4th of 2024 Census by Service Type: Incenter Hemodialysis: 41 Home Peritoneal Dialysis: 24			V 0000			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Kerrey Thornton

Director of Operations

12/23/2024

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards 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 disclosable 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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 0101 Bldg. 00	<p>Home Hemodialysis: 7</p> <p>Total Active Census: 72</p> <p>Isolation Room/Waiver: N/A Facility Constructed prior to February 9, 2009.</p> <p>Fresenius Medical Care Noblesville was found to be out of compliance with the Conditions for Coverage 42 CFR 494.90, Patient Plan of Care.</p> <p>Abbreviations:</p> <p>RN Registered Nurse ICHD In-center Hemodialysis</p> <p>PCT Patient Care Technician HHD Home Hemodialysis</p> <p>RD Registered Dietician PD Peritoneal Dialysis</p> <p>MSW Masters Social Worker CM Clinical Manager</p> <p>494.20 COMPLIANCE WITH FED/STATE/LOCAL LAWS</p> <p>Based on observation, record review, and interview, the facility failed to secure oxygen cylinders in stands and/or racks in 1 of 1 facility reviewed.</p> <p>Findings Include:</p> <p>1. A policy titled, "Emergency Administration of Oxygen" indicated but was not limited to, "Unless in use, secondary (reverse) cylinders/tanks must be: Secured in racks or rolling stands in a storage</p>			V 0101	<p><u>V-101</u></p> <p>On December 16, 2024, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Emergency Administration of Oxygen</p>		01/03/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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
	<p>area or dedicated area for oxygen".</p> <p>2. During an observation on 11/25/2024 at 11:25 AM, the treatment floor evidenced two oxygen cylinders next to the lobby door sitting directly on the floor and not secured in a rack or rolling stand.</p> <p>3. During an interview on 11/25/2024 at 11:28 AM, RN 6 indicated not being aware of oxygen storage requirements.</p> <p>4. During an interview on 11/25/2024 at 3:18 PM, the Administrator indicated that oxygen canisters should not be sitting directly on the floor.</p>				<p>Emphasis will be placed on:</p> <p>Oxygen cylinders must be secured in an area where they will not fall.</p> <p>A primary oxygen cylinder must be:</p> <p>Secured to the crash cart.</p> <p>Checked on a weekly basis to ensure there is oxygen in the tank and documentation of weekly check must be recorded on the crash cart log sheet or oxygen cylinder log sheet.</p> <p>Do not store oxygen cylinders near water heaters, furnaces, sources of heat, flame, combustible material or in small or unventilated storage areas.</p> <p><u>Unless in use, secondary (reserve) cylinders/tanks must be:</u></p> <p>Secured to racks or rolling stands in a storage area or dedicated area for oxygen.</p> <p>Do not store oxygen cylinders near water heaters, furnaces, sources of heat, flame, combustible material or in small or unventilated storage areas.</p> <p>Effective December 19, 2024, the Clinical Manager or the Charge Nurse will conduct infection control audits 3 times per week, with alternating shifts with focus on ensuring all oxygen cylinder tanks are secured in racks or rolling stands per policy, utilizing Infection Control Monitoring Tool</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE			STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060		
(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	
			<p>for 2 weeks and then 2 times per week for an additional 4 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.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>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.</p> <p>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.</p> <p>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.</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE			STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060		
(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 0113 Bldg. 00	<p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE</p> <p>Based on observation, record review and interview, the facility staff failed to provide appropriate infection control practices that would assist in preventing the spread of communicable diseases in 2 of 2 dialysis station set ups observed, (RN 6, PCT 2), 2 of 2 dialysis station disinfections observed, (PCT 3, PCT 2), 1 of 2 observations of discontinuing treatment (RN 6), and 1 of 1 Home Program observations (RN 4).</p> <p>Finding include:</p> <p>1. A 11/06/2023 policy titled, "Personal Protective Equipment" indicated but was not limited to, "Staff must remove gloves and wash hands after: Patient care ... Exposure to blood and body fluids ... Touching any surfaces within the patient station ... If hands are not visibly soiled, an alcohol-based sanitizer may be used ... Always perform hand hygiene after glove removal ... Avoid touching surfaces with gloved hands that</p>	V 0113	<p>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.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 01/03/2025.</p> <p><u>V-113</u></p> <p>On December 16, 2024, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Personal Protective Equipment</p> <p>Emphasis will be placed on:</p> <p>Staff must remove gloves and wash hands after: Patient care Exposure to blood and body fluids Touching any surfaces within the patient station</p>	01/03/2025	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024

FORM APPROVED

OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP CODE 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (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
	<p>will be touched with ungloved hands (for ex. patient chart and computers)".</p> <p>2. During an observation on 11/25/2024 at 10:20 AM, RN 6 was observed setting up a dialysis station. RN 6 removed her gloves, hand hygiene was not completed, walked over to the supplies and obtained a laboratory tube, returned to the station and put clean gloves back on without performing hand hygiene. RN 6 failed to perform appropriate hand hygiene with glove use.</p> <p>3. During an observation on 11/25/2024 at 10:25 AM, RN 6 failed to complete hand hygiene prior to putting on clean gloves when discontinuing a treatment at Station #7.</p> <p>4. During an observation on 11/26/2024 at 10:22 AM, PCT 2 was observed continually adjusting her face mask, face shield, hair throughout the disinfection of the dialysis station, Station 11, with gloved hands. PCT 2 failed to change gloves and/or complete hand hygiene.</p> <p>5. During an observation on 11/26/2024 at 10:37 AM, PCT 2 was setting up Station #2. Clean gloves donned, PCT 2 adjusted her facemask and hair several times while stringing the dialysis machine, and spiked the new saline bag, failing to complete hand hygiene and change gloves when contaminated.</p> <p>6. During an observation on 12/2/2024 at 11:07 AM, RN 4 removed Patient #4's personal items from the bedside tray with clean gloves on, then placed her face shield on her head, set a clean under pad on the bedside tray, placed clean supplies on the under pad and completed venipuncture on Patient #4. RN 4 failed to change gloves once contaminated and perform</p>				<p>If hands are not visibly soiled, an alcohol-based hand sanitizer may be used.</p> <p>Always perform hand hygiene after glove removal.</p> <p>Avoid touching surfaces with gloved hands that will be touched with ungloved hands (for ex. patient charts and computers.)</p> <p>Effective December 19, 2024, the Clinical Manager or the Charge Nurse will conduct infection control audits 3 times per week, with alternating shifts with focus on ensuring staff remove gloves after patient care, perform hand hygiene per policy, utilizing Infection Control Monitoring Tool for 2 weeks and then 2 times per week for an additional 4 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.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP CODE 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (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	
	<p>appropriate hand hygiene prior to the venipuncture.</p> <p>7. During an interview on 11/26/2024 at 11:30 AM, PCT 2 indicated that contaminated gloves should be removed, hands cleaned, and new gloves donned.</p>			<p>Correction prior to presenting to the QAPI Committee monthly.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 01/03/2025.</p>			
V 0147 Bldg. 00	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE						

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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
	<p>Based on observation, record review, and interview, the facility failed to ensure a clean under pad was placed beneath the Central Venous Catheter (CVC) limbs prior to discontinuing treatment in 2 of 2 CVC observations. (Patient #2, Patient # 4)</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. A policy 11/4/2024 policy titled, "Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer" indicated but was not limited to, "Prior to Termination Preparation: 5. Ensure that a clean under pad is below the catheter limbs to protect the work area and the clothing". 2. During an observation on 11/25/2024 at 9:56 AM, PCT 1 failed to replace the soiled under pad when discontinuing treatment of a CVC, Patient #2. 3. During an observation on 11/25/2024 at 10:27 AM, PCT 1 failed to replace the soiled under pad when discontinuing treatment of a CVC, Patient #4. 4. During an interview on 12/4/2024 at 12:55 PM, PCT 1 indicated the under pad used at initiation of treatment is used at discontinuation of treatment and not changed unless observed to be soiled. The under pad remains on the patient throughout treatment. 			V 0147	<p><u>V-147</u></p> <p>On December 16, 2024, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Termination of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer</p> <p>Emphasis will be placed on: Follow the steps below to prepare for the termination of dialysis: Check volume of each catheter limb to determine the amount of heparin or other locking solution to be instilled into each catheter lumen. Draw up heparin or other locking solution as prescribed for each catheter lumen. Don gown and full-face shield with mask (or protective eyewear with full side shield and mask). Place mask on patient, perform hand hygiene then don new gloves. At any time during the termination process, if gloves are visibly contaminated, remove gloves, perform hand hygiene, and don new gloves. When dialysis treatment is complete, the machine will alarm, indicating that the prescribed time of treatment has been completed</p>		01/03/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE			STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060		
(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	
			<p>and fluid goal achieved. Verify and acknowledge treatment completion.</p> <p><u>Ensure that a clean under pad is below the catheter limbs to protect the work area and the clothing.</u></p> <p>Collect post dialysis blood samples if ordered, according to the Policies & Procedures.</p> <p>Effective December 19, 2024, the Clinical Manager or the Charge Nurse will conduct infection control audits 3 times per week, with alternating shifts with focus on ensuring that a clean under pad is below the catheter limbs to protect the work area and clothing per policy, utilizing Infection Control Monitoring Tool for 2 weeks and then 2 times per week for an additional 4 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.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE			STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060		
(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 0184 Bldg. 00	494.40(a) ENVIRONMENT-SECURE & RESTRICTED	V 0184	<p>Correction prior to presenting to the QAPI Committee monthly.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 01/03/2025.</p>	01/03/2025	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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
	<p>Based on observation, record review, and interview, the facility failed to keep the water room locked and secure for 1 of 1 facility reviewed.</p> <p>Findings include:</p> <p>1. A 09/05/2023 policy titled, "Physical Security and Facility Access" indicated but was not limited to, "Water Treatment Area Security: Restricted access must be maintained to prevent unwanted tampering with the water treatment equipment. The facility must be maintained to prevent unwanted entry by outside persons not involved in the daily operation of the clinic. This is accomplished by: Locking all doors that allow access to the water treatment equipment. No exterior building door will be left unlocked unless under the continual supervision of a facility staff member".</p> <p>2. During the flash tour observation on 11/25/2024 at 9:25 AM, the water room evidenced an unlocked/unsecured door. Staff were not present inside the water room.</p> <p>3. During an interview on 11/25/2024 at 09:30 AM, the Area Team Operations Manager (ATOM) indicated the water room should be locked/secured when unattended by staff.</p> <p>4. During an interview on 11/26/2024 at 12:55 PM, the Biomed indicated the water room is to be locked when unattended by staff.</p>				<p>On December 16, 2024, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Physical Security and Facility Access</p> <p>Emphasis will be placed on:</p> <p>Water Treatment Area Security Restricted access <i>must</i> be maintained to prevent unwanted tampering with the water treatment equipment. The facility must be maintained to prevent unwanted entry by outside persons not involved in the daily operation of the clinic. This is accomplished by:</p> <ul style="list-style-type: none"> - Locking all doors that allow access to the water treatment equipment. - No exterior building door will be left unlocked unless under the continual supervision of a facility staff member. <p>Effective December 19, 2024, the Clinical Manager or the Charge Nurse will conduct infection control audits 3 times per week, with alternating shifts with focus on ensuring the water room is locked and secured per policy, utilizing Infection Control Monitoring Tool for 2 weeks and</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE			STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060		
(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	
			<p>then 2 times per week for an additional 4 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.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>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.</p> <p>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.</p> <p>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.</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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 0196 Bldg. 00	<p>494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY</p> <p>Based on record review and interview, the facility failed to ensure chlorine testing was completed every 4 hours with one staff member being a licensed RN for 1 of 1 facility reviewed.</p> <p>Finding include:</p> <p>1. A policy dated 11/07/2022, titled "Carbon Filtration Monitoring for Incenter Central Water Systems Policy" indicated but was not limited to, "Two trained staff members, one of whom must be a licensed RN, will perform and verify total chlorine testing. Both staff members must be present. One staff member will perform the test while the other staff member observes the test being performed. If both staff members are unable to be present at the time of testing, then each must perform the test individually, comparing the results ... Worker Carbon Filter ... When to test ... prior to the initiation of the first patient treatment of the day and at a minimum of every four hours".</p>			V 0196	<p>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.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 01/03/2025.</p> <p>V-196</p> <p>On December 16, 2024, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Carbon Filtration Monitoring for Incenter Central Water Systems Policy</p> <p>Emphasis will be placed on:</p> <p>Verification of Test Results: Two trained staff members, one of whom must be a licensed RN, will perform and verify total chlorine testing. To verify: Both staff members must be present. One staff member will</p>		01/03/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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
	<p>2. A document titled "Post RO [Reverse Osmosis] with 1 Holding Tank - TCL -1[Total Chlorine Log] (54641)" indicated on 10/08/2024 PCT 4 and the Area Team Operations Manager (ATOM) obtained the initial chlorine test for the treatment day. The facility failed to ensure a licensed RN completed the chlorine/chloramine test.</p> <p>3. A document titled, Post Worker Carbon Tank - TCL -1" indicated a chlorine test completed on 10/08/2024 at 8:15 AM by RN 6.</p> <p>4. A document titled, Post Worker Carbon Tank - TCL -1" indicated the following late chlorine test completed: 11/16/2024: 3:51 AM and 8:15 AM (4 hours and 24 minutes), 11/19/2024: 4:40 AM and 9:44 AM (5 hours and 4 minutes), 11/24/2024: 11:30 AM with no additional chlorine test completed. Last treatment of the day ended at 4:03 PM (4 hours and 33 minutes), 10/04/2024: 7:45 AM and 11:49 AM (4 hours and 4 hours and 4 minutes), 10/24/2024: 5:30 AM and 9:40 AM (4 hours and 10 minutes), 09/07/2024: 4:45 AM and 8:58 AM (4 hours and 13 minutes) and 09/10/2024: 7:40 AM and 12:21 AM (4 hours and 41 minutes).</p> <p>5. A treatment sheet for Patient #5, dated 11/24/2024, indicated an end treatment time of 4:03 PM.</p> <p>6. During an interview on 11/26/2024 at 2:51 PM, the Administrator indicated that the last treatment of the day on 11/24/2024 ended at 4:03 PM, Patient #5. Staff should have completed an additional chlorine check by 3:30 PM.</p> <p>7. During an interview on 11/26/2024 at 1:45 PM, the ATOM indicated that an RN and another trained staff member must complete each chlorine</p>				<p>perform the test while the other staff member observes the test being performed.</p> <p>If both staff members are unable to be present at the time of testing, then each must perform the test individually, comparing results. In this case, verification will be determined by both staff members obtaining similar results.</p> <p>When to test:</p> <p>Prior to the initiation of the first patient treatment of the day and at a minimum of every four hours.</p> <p>Effective December 19, 2024, the Clinical Manager and/or Charge Nurse will monitor total chlorine testing in TMS by observing the daily logs 2 times per day times for 2 weeks, then weekly for 2 months, then monthly to ensure testing is done by two staff members, one being a Registered Nurse, and within 4 hours. If any opportunities are identified the Clinical Manager will immediately bring them to the attention of the Director of Operations who will address the issue with the appropriate staff. Once compliance is sustained, the Governing Body will decrease frequency to monthly per the QAI calendar utilizing the Water & Dialysate Observation in the Clinic Audit Checklist. A summary of the monitoring will be reported in the monthly QAPI meeting to ensure</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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
	<p>test. The ATOM verified that an RN did not sign off on the chlorine test completed on 10/08/2024. She attributed this oversight to consistently changing float staff and/or computer sign-off failure, which led to charting values under the wrong user. Staff should complete chlorine checks every 4 hours.</p> <p>8. During an interview on 11/26/2024 at 1:50 AM, the Director of Operations indicated chlorine checks can be completed by two qualified staff members, not necessarily one being an RN, but will check the policy.</p> <p>9. During an interview on 11/26/2024 at 2:26 PM, the Administrator indicated staff should complete chlorine checks every 4 hours.</p> <p>10. During an interview on 11/26/2024 at 4:00 PM, the Director of Operations indicated that on 10/08/2024, if the ATOM did not sign out of the computer after documenting, the RN could have completed the chlorine test and just mistakenly charted it under the ATOM.</p>				<p>compliance.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152556	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE			STREET ADDRESS, CITY, STATE, ZIP CODE 165 SHERIDAN RD NOBLESVILLE, IN 46060		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (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 0520 Bldg. 00	<p>494.80(d)(2) PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO</p> <p>Based on record review and interview, the facility failed to ensure a monthly care plan was completed for 1 of 1 unstable patient record review. (Patient #1)</p> <p>Findings Include:</p> <p>1. A 07/03/2023 policy titled, "Comprehensive Interdisciplinary Assessment and Plan of Care" indicated but was not limited to, "The comprehensive Interdisciplinary Assessment and Plan of Care must be developed and implemented by the interdisciplinary team (IDT) consisting of at a minimum, the patient or patient's designee, a registered nurse, the patient's attending physician (or physician extender where allowed by State regulations), qualified master's degree level social worker and qualified registered dietician ... The plan of care should be signed at the time of the interdisciplinary team meeting for those attending in person. If unable to sign at the time of the meeting or if attending remotely, the care plan must be signed by the IDP member within 30 days of the interdisciplinary team meeting ... Unstable patients must be reassessed by the IDT monthly. Monthly reassessment and any POC updates related to the reason the patient is considered "unstable" must be documented until the issues have been resolved or the IDT (including the</p>	V 0520	<p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 01/03/2025.</p> <p>V520</p> <p>On December 16, 2024, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Comprehensive Interdisciplinary Assessment and Plan of Care</p> <p>Emphasis will be placed on:</p> <p>Unstable patients must be reassessed by the IDT monthly. Monthly re-assessment and any POC updates 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. The following are unstable criteria:</p> <p>Extended or Frequent hospitalizations: a. Hospitalization of more than 15</p>	01/03/2025	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>patient if possible) determines that the condition is chronic ... the physician is responsible for ensuring the completion of the medical portion of the CIA and reviewing the completed interdisciplinary CIA and Plan of Care".</p> <p>2. A review of Patient #1's medical record evidenced an admission date of 08/29/2024. The initial care plan was completed on 10/31/2024, 61 days later, and the patient was deemed unstable. The RN and patient did not sign the completed care plan. No one provided documentation to ensure the staff informed the patient of the meeting outcome. The staff did not complete a follow-up unstable care plan scheduled on 11/30/2024.</p> <p>3. During an interview on 11/25/2024 at 12:50 PM, the medical director indicated that RN 6 was new and needed continual assistance completing tasks, specifically care plans.</p> <p>4. During an interview on 12/2/2024 at 9:44 AM, the Administrator indicated that staff should assess unstable patients and complete a plan of care monthly. Staff did not complete Patient #1's monthly care plan in November 2024.</p> <p>5. During an interview on 12/2/2024 at 9:48 AM, the Interim Clinic Manager indicated the social worker was responsible for notifying staff when all care plans were due. The Interim Clinic Manager indicated that the staff missed the monthly unstable care plan due to the social worker's vacation.</p> <p>6. During an interview on 12/2/2024 at 10:02 AM, the Interim Clinic Manager indicated she could not find a signed 10/30/2024 initial/unstable care plan in the patient's clinical record.</p>				<p>days with discharge occurring within the last 30 days, or</p> <p>b. More than 3 admissions in the last 30 days</p> <p>OR</p> <p>Marked deterioration in health status – IDT to identify and document the specific reasons, such as:</p> <p>a. Change in ambulation severe enough to interfere with the patient's ability to follow aspects of the treatment plan.</p> <p>b. Hypotension, restlessness, pruritus or other symptoms severe enough to prevent completion of majority of dialysis treatments.</p> <p>c. Sudden onset of recurrent cardiac arrhythmias;</p> <p>d. Recurrent infections [not requiring hospitalization],</p> <p>e. Chronic congestive heart failure with chronic hypotension,</p> <p>f. Advanced or metastatic cancer or other organ system disease which interferes with the patient's ability to follow aspects of the treatment plan,</p> <p>g. Chronic or recurrent peritonitis</p> <p>OR</p> <p>Significant change in psychosocial needs</p> <p>a. Change in mentation or psychosocial needs severe enough to interfere with the patient's ability to follow aspects of the treatment plan and may include situations related to immediate family members. (Any patient considered at risk for</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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
	<p>7. During an interview on 12/2/2024 at 2:09 PM, the Interim Clinic Manager indicated assisting the new nurse with training on care plans and other RN tasks but has been short on time.</p> <p>8. During an interview on 12/3/2024 at 2:20 PM, RN 6 indicated that care plans, when deemed unstable, should be completed monthly. RN 6 further indicated that as a new RN to the facility, she was given a lot of responsibilities too quickly and has difficulty completing RN tasks, including care plans, in a timely manner. Staff did not complete Patient #1's care plan for November 2024 due to time constraints. The social worker provides her with a list of care plans to be completed for the month but does not provide this list in a more manageable time frame. If received earlier, RN 6 may be able to complete them on time. She continues learning to document assessment findings in the care plan and correctly complete orders.</p>				<p>involuntary discharge or transfer must be considered "unstable" under this category.) OR Concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis a. Albumin < 4.0 for any modality or weight loss > 10% dry body weight plus b. Hgb < 10 for any modality plus c. Kt/V meeting the following criteria for 3 months i. eKt/V < 1.0 External POC Report Page 7 of 9 ii. SpKt/V < 1.2 for Incenter HD on 3x/week iii. Kt/V < 1.7 for PD</p> <p>By December 19, 2024, the interdisciplinary team will review all patients in the facility for their stability status. Any patients found that meets the unstable requirements, will have an unstable assessment and plan of care completed by January 3, 2024.</p> <p>Effective December 19, 2024, the Clinical Manager or Charge Nurse will conduct weekly audits utilizing ePOC audit tool for (4) weeks. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly for (3) months then resume regularly scheduled audits based on the QAPI calendar. Monitoring will be done through the ePOC audit tool.</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE			STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060		
(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
			<p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>The Clinica 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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The QAPI and Governing Body</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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 0540 Bldg. 00	494.90 CFC-PATIENT PLAN OF CARE Based on record review and interview, the facility failed to ensure the initial plans of care were developed for new admission patients. (See V 542) The cumulative effect of these systemic problems has resulted in the dialysis center's inability to ensure the provision of quality health care in a safe environment for the condition of participation 42 CFR 494.90 Patient Plan of Care.			V 0540	<p>minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 01/03/2025.</p> <p>V540 The Governing Body takes seriously the management of the day-to-day operations of the facility and their responsibilities for ensuring safe dialysis treatments for all patients receiving hemodialysis at the facility, inclusive of, but not limited to ensuring the plan of care is consistently implemented to prevent serious injury, serious harm, serious impairment, or death. The Governing Body met initially on December 9, 2024, and again on December 18, 2024 after receipt of the Statement of Deficiencies to review and develop the following Plan of Correction ensuring that deficiencies are addressed, both immediately and with long term resolution. The Governing Body began meeting weekly beginning December 18, 2024 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</p>		01/03/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE			STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060		
(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	
			<p>will determine when the frequency of these meetings may be reduced to the regular quarterly schedule. Effective immediately:</p> <p>The Director of Operations 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 QAI Committee.</p> <p>A specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) agenda.</p> <p>The QAI Committee is responsible for reviewing and evaluating the Plan of Correction to ensure it is effective and providing resolution of the issues.</p> <p>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.</p> <p>The Governing Body, at its meeting of December 18, 2024, 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</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE			STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060		
(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 0542 Bldg. 00	<p>494.90(a) POC-IDT DEVELOPS PLAN OF CARE</p> <p>Based on record review and interview the facility failed to ensure staff completed a Plan of Care for 4 of 5 Incenter Hemodialysis patients record reviews. (Patient #1, #2, #3, #5)</p> <p>Findings include:</p> <p>1. A 07/03/2024 policy titled, "Comprehensive Interdisciplinary Assessment and Plan of Care" indicated but was not limited to, "An Interdisciplinary Comprehensive Assessment and Plan of Care must be completed by the</p>	V 0542	<p>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.</p> <p>Minutes of the Governing Body and QAI meetings, as well as monitoring forms and educational documentation will provide evidence of these actions, the Governing Body's direction, and oversight and the QAI Committees ongoing monitoring of facility activities. These are available for review at the facility.</p> <p>The responses provided for V 542 describe, in detail, the processes and monitoring steps taken to ensure that all deficiencies cited within this Condition are corrected to ensure ongoing compliance.</p> <p>V542</p> <p>- On December 16, 2024, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Comprehensive Interdisciplinary Assessment and Plan of Care</p>	01/03/2025	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>interdisciplinary team members, per the frequency outlined in the Conditions for Coverage ... The Comprehensive Interdisciplinary Assessment and Plan of Care must be developed and implemented by an interdisciplinary team (IDT) consisting of at a minimum, the patient or patient's designee, a registered nurse, the patient's attending physician (or physician extender where allowed by State regulations), qualified master's degree level social worker and qualified registered dietitian ... The Comprehensive Assessment and Plan of Care (adult patient) must be completed electronically in the patient's medical record. The Plan of care should be signed at the time of the interdisciplinary team meeting for those attending in person. If unable to sign at the time of the meeting or if attending remotely, the care plan must be signed by the IDP member within 30 days of the interdisciplinary team meeting ... The patient's Plan of Care will be guided and developed based on the findings identified in the Comprehensive Interdisciplinary Assessment ... Patient stability must be reviewed monthly ... The frequency of the Comprehensive Interdisciplinary Assessment and Plan of Care are determined by the stability of the patient as determined by the physician, with input from the IDT".</p> <p>2.The medical record for Patient #1 indicated an admission date of 08/29/2024. The initial RN, social worker, and dietician completed the comprehensive assessments; however, the plan of care was not developed and implemented within 30 days or 13 treatments. The care plan meeting was on 10/31/2024, 63 days after admission. The Registered Nurse or patient did not sign the 10/31/2024 initial care plan.</p> <p>3. The medical record for Patient #2 indicated an admission date of 08/27/2024. The initial RN,</p>				<p>Emphasis will be placed on:</p> <p>An Interdisciplinary Comprehensive Assessment and Plan of Care must be completed by the interdisciplinary team members, per the frequency outlined in the Conditions for Coverage.</p> <p>The Comprehensive Interdisciplinary Assessment and Plan of Care must be developed and implemented by an interdisciplinary team (IDT) consisting of at a minimum, the patient or patient's designee, a registered nurse, the patient's attending physician (or physician extender where allowed by State regulations), qualified master's degree level social worker and qualified registered dietitian.</p> <p>The Comprehensive Assessment and Plan of Care (adult patient) must be completed electronically in the patient's medical record. The Plan of Care should be signed at the time of the interdisciplinary team meeting for those attending in person. If unable to sign at the time of the meeting or if attending remotely, the care plan must be signed by the IDP member within 30 days of the interdisciplinary team meeting.</p> <p>The patient's Plan of Care</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>social worker, and dietician comprehensive assessments were completed however the facility failed to ensure the initial care plan was developed and implemented.</p> <p>4. The medical record for Patient #3 indicated an admission date of 09/02/2024. The initial RN, social worker, and dietician completed the comprehensive assessments; however, the facility failed to ensure the initial care plan was developed and implemented.</p> <p>5. The medical record for Patient #5 indicated an admission date of 08/12/2024. The initial social worker and dietician completed the comprehensive assessments; however, the initial RN assessment was not completed. The facility staff failed to complete the initial RN comprehensive assessment and failed to ensure the initial care plan was developed and implemented.</p> <p>6. During an interview on 12/3/2024 at 2:20 PM, RN 6 indicated that care plans, when deemed unstable, should be completed monthly. RN 6 further indicated that as a new RN to the facility, she was given a lot of responsibilities too quickly and has difficulty completing RN tasks, including care plans, in a timely manner. Staff did not complete Patient #1's care plan for November 2024 due to time constraints. The social worker provides her with a list of care plans to be completed for the month but does not provide this list in a more manageable time frame. If received earlier, RN 6 may be able to complete them on time. She continues learning to document assessment findings in the care plan and correctly complete orders.</p>				<p>will be guided and developed based on the findings identified in the Comprehensive Interdisciplinary Assessment.</p> <p>Patient stability must be reviewed monthly. The interdisciplinary team will offer input to the attending physician who will determine whether the patient is stable or unstable on the criteria included in this policy.</p> <p>The frequency of the Comprehensive Interdisciplinary Assessment and Plan of Care are determined by the stability of the patient as determined by the physician, with input from the IDT.</p> <p>By December 19, 2024, the interdisciplinary team will review 100% all patient records inclusive of new patients for complete comprehensive assessments and plans of care. Any patients identified without a comprehensive assessment and plan of care completed fully will have a new plan of care meeting scheduled. The Interdisciplinary team will meet and have all Comprehensive Assessments and Plans of Care completed by January 3, 2025.</p> <p>Effective December 23, 2024 the Clinical Manager or Charge Nurse will conduct weekly audits utilizing ePOC audit tool for (4) weeks. Once compliance is sustained at</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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
	<p>7. During an interview on 12/3/2024 at 2:35 PM, the Administrator indicated staff did not complete the initial care plans for Patients #2, #3, and #5. Staff should have completed Patient #1's care plan in 30 days or 13 treatments and signed by the RN.</p> <p>8. During an interview on 12/3/2024 at 11:06 AM, the Director of Operations indicated that the staff provided all assessments for Patients #1, #2, and #3; however, the RN did not complete the comprehensive assessment for Patient #5.</p> <p>9. During an interview on 11/25/2024 at 12:50 PM, the medical director indicated that RN 6 was new and needed continual assistance completing tasks, specifically care plans. .</p>				<p>100%, the Governing Body will decrease frequency to monthly for (3) months then resume regularly scheduled audits based on the QAPI calendar. Monitoring will be done through the ePOC audit tool.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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 0715 Bldg. 00	<p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P</p> <p>Based on observation, record review, and interview, the facility staff failed to ensure expired supplies and medications were appropriately discarded, medications were secured from unauthorized access, and pre-drawn medications were properly labeled for 1 of 1 facility reviewed.</p> <p>Findings include:</p> <p>1. A 04/05/2021 policy titled, "Storage of Supplies" indicated but was not limited to, "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".</p> <p>2. A 02/06/2023 policy titled, "Medication Preparation and Administration" indicated but was not limited to, "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 ... Securement: All medications will be kept in a</p>			V 0715	<p>address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 01/03/2025.</p> <p><u>V-715</u></p> <p>On December 16, 2024, the Director of Operations held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on the Policy.</p> <p>Storage of Supplies Medication Preparation and Administration</p> <p>Emphasis will be placed on:</p> <p>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.</p> <p>Expiration dates for all stored medications are to be monitored</p>		01/03/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____		X3) DATE SURVEY COMPLETED 12/04/2024
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE			STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060		
(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	
	<p>locked cabinet except when in use. One key to the medication cabinet will be kept by the charge nurse/team leader. The Clinical Manager will retain a spare key, kept in secure location. The key to the medication cabinet will be kept in a secure location when the facility is closed. Only the clinical manager, charge nurse and team leader will have access to the location. When the charge nurse/team leader leaves the treatment area, the key will be left in the possession of other qualified, licensed personnel ... 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 ... Oral medications not being administered immediately must also be labeled as indicated above".</p> <p>3. A 05/01/2023 policy titled, "Emergency Medications, Equipment and Supplies" indicated but was not limited to, "The emergency cart must be: Locked when not in use, checked monthly or after use for contents, expiration date".</p> <p>4. During an observation on 11/25/2024 at 9:25 AM, the water room evidenced one bottle of MesaLabs Standard Buffer Solution (solution used to calibrate meters for pH and conductivity) expired on 10/11/2024.</p> <p>5. During an observation of the treatment floor on 11/25/2024 at 10:12 AM the storage drawer evidenced one box of Crit-Line CLiC Blood chambers (used on the dialysis machine to assist in determining fluid removal) expired on 10/31/2024.</p> <p>6. During on observation of the treatment floor on 11/25/2024 at 10:37 AM, the surveyor found the</p>		<p>on a monthly basis.</p> <p>Expired medications are to be discarded via Fresenius Kidney Care off-site return program or in accordance with local and/or state law.</p> <p>Any open multi dose vials must be discarded 28 days after opening or per manufacturer's expiration date.</p> <p>CDC immunization program states vaccine are to be discarded per manufacturer's expiration date The following steps must be taken for the securement:</p> <p>All medications will be kept in a locked cabinet except when in use.</p> <p>One key to the medication cabinet will be kept by the charge nurse/team leader. The Clinical Manager will retain a spare key, kept in a secure location.</p> <p>The key to the medication cabinet will be kept in a secure location when the facility is closed. Only the clinical manager, charge nurse and team leader will have access to the location.</p> <p>When the charge nurse/ team leader leaves the treatment area, the key will be left in the possession of other qualified, licensed personnel.</p> <p>Labeling Reconstituted Medication Solutions and Syringe:</p> <p>All medications in syringes not being administered immediately shall be labeled appropriately with the name of the</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024

FORM APPROVED

OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>medication cabinet unlocked/unsecured. This cabinet housed all treatment medications and emergency medications that did not require refrigeration. Five medication cups with patient labels affixed to the side contained oral medications. The label did not provide the staff initials or the time staff set up the medications. Fifteen vials of 100 milligrams (mg) Venofer (Intravenous medication used to treat anemia) were sitting on the counter at the medication preparation area, unsecured and unattended.</p> <p>7. During an observation of the treatment floor on 11/25/2024 at 11:03 AM, the unsecured medication cabinet evidenced Nalozone Hydrochloride 0.4 mg vials (medication used to treat Opioid-induced depression) expired on 09/2024.</p> <p>8. During an observation of the treatment floor on 11/25/2024 at 11:14 AM, the medication refrigerator evidenced five doses of Prevnar 13 (pneumonia vaccine) and eight vials of Parsabiv 10 mg (medication used to treat an overactive parathyroid). All medications expired on 09/2024.</p> <p>9. During an observation of the treatment floor on 11/25/2024 at 11:14 AM, the medication preparation counter evidenced five patient medication cups containing unattended oral medications by licensed staff. RN 6, the only RN working on the treatment floor, was observed assisting a patient with treatment at Station 6.</p> <p>10. During an observation of the treatment floor on 11/25/2024 at 11:17 AM, the surveyor found the emergency crash cart unlocked/unsecured with medications inside.</p> <p>11. During an observation of the treatment floor on 11/25/2024 at 11:23 AM, a lockbox was located</p>				<p>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."</p> <p>Reconstituted medication admixtures shall also include on the label the date and time the solution was prepared.</p> <p>Filled syringes do not have to be labeled if drawn up and administered immediately. These unlabeled, filled syringes must not be placed down at any time. Only one unlabeled, filled syringe can be drawn up and administered at one time.</p> <p>Oral medications not being administered immediately must also be labeled as indicated above.</p> <p>Effective December 19, 2024, the Clinical Manager or the Charge Nurse will conduct infection control audits 3 times per week, with alternating shifts with focus on ensuring that no expired supplies and medications are in the treatment or storage area, and all medications are secured if not immediately administered per policy, utilizing Infection Control Monitoring Tool for 2 weeks and then 2 times per week for an additional 4 weeks or until 100% compliance is achieved. The Governing Body will determine</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>on the counter in front of the nurse's station near the patient scale/handwashing station and exit door to the lobby. The lockbox was left open and unattended and contained 10 Heparin (medication used to prevent clotting during dialysis) vials, 30,000 units/30 milliliters plus one partially used vial. The surveyor found 10-milliliter syringes and patient medication labels in an opened lockbox.</p> <p>12. During an observation of the treatment floor on 11/25/2024 at 11:27 AM, the surveyor found a storage cart evidencing thirty-six clear/red top laboratory tubes to have expired on 09/30/2024.</p> <p>13. During an observation of the Home Dialysis Area on 11/25/2024 at 11:45 AM a drawer in the treatment/training room evidenced 22 Chloraprep Single Swabsticks (used to disinfect skin) that had expired on 07/2024.</p> <p>14. During an observation of the Home Dialysis Area on 11/25/2024 at 11:50 AM, a cabinet in the laboratory area evidenced Culture Swab Plus (used culture skin) that had expired on 10/16/2024 and clear/red top laboratory tubes expired on 10/31/2024.</p> <p>15. During an observation of the Home Dialysis Area on 11/25/2024 at 11:59 AM, the Home Administrative Assistant was asked where the Home Dialysis medications were kept. She walked the surveyor to the cabinet that housed the medications and found the cabinet was locked. She left and returned with a key and opened the cabinet for the surveyor.</p> <p>16. During an observation on 11/27/2024 at 11:27 PM the nurse's station medication counter evidenced a pre-filled syringe of Venofer for Patient #8, left unattended. A lockbox at the</p>				<p>on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar.</p> <p>The Medical Director will review the results of audits each month at the QAPI Committee meeting monthly.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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
	<p>nurse's station evidenced Heparin inside, which was unlocked/unattended.</p> <p>17. During an observation on 12/04/2024 at 9:32 AM, PCT 1 was observed drawing up Heparin before the patient arrived. PCT 1 drew up the medication, placed a label on the syringe, and placed the syringe back into the Heparin lockbox, failing to label the syringe with the initials of the preparer and the time staff prepared the medication.</p> <p>18. During an interview on 11/25/2024 at 10:52 AM, the InCenter Hemodialysis Administrative Assistant indicated having access to all medications. She assists the RN with ordering, organizing, and monitoring for expired medications. She also indicated that she was not a Licensed nurse but was a PCT; however, she does not work as a PCT anymore.</p> <p>19. During an interview on 11/25/2024 at 10:52 AM, RN 6 indicated that medication cabinets are left unlocked all day and secured at the end of the day. If leaving the treatment floor, staff would lock the cabinet. Venofer was left out on the counter throughout the day. RN 6 indicated that she frequently assists with initiating and discontinuing patient treatments throughout the day, and medications are unsecured during this time.</p> <p>20. During an interview on 11/25/2024 at 11:28 AM, RN 6 indicated that expired supplies should be discarded and not used. She was unaware the crash cart was not locked and had personally inventoried it this past Sunday.</p> <p>21. During an interview on 11/25/2024 at 12:14 PM, the Home Program Manager indicated that only</p>				<p>the Statement of Deficiency, is effective and is providing resolution of the issues.</p> <p>The QAPI and Governing Body minutes, education and monitoring documentation, are available for review at the clinic.</p> <p>Completion Date: 01/03/2025.</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 12/26/2024
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152556		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 12/04/2024	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE NOBLESVILLE				STREET ADDRESS, CITY, STATE, ZIP COD 165 SHERIDAN RD NOBLESVILLE, IN 46060			
(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
	nurses can access the medications. The manager then questioned whether the surveyor had asked the Administrative Assistant to open the cabinet. It was advised that the assistant was only asked to show the surveyor where the medications were located. The Home Program Manager was provided all supplies found to be expired in the home department. 22. During an interview on 11/25/20204 at 12:25 PM, RN 4 stated that all expired supplies should be discarded and that only licensed nurses should have access to medications.						