STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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: September 27th, 28th, 29th, and 30th of 2021 Facility ID: 002902 Census: 21 In-center Hemodialysis 5 Home Peritoneal Dialysis 1 Home Hemodialysis At this Emergency Preparedness survey, Fresenius Medical Care Elwood, was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62. QR Completed 10/14/2021 A4	E 0000		
V 0000 Bldg. 00	This visit was for a federal core ESRD (Core) recertification survey in conjunction with a COVID-19 infection control survey. Survey Dates: September 27th, 28th, 29th, and 30th of 2021 Facility ID: 002902 Census: 21 In-center Hemodialysis	V 0000		

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	5 Home Peritoneal Dialysis 1 Home Hemodialysis			
V 0113 Bldg. 00	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. Based on observation, record review, and interview, the facility failed to ensure staff were changing gloves and washing hands appropriately when soiled in 1 of 4 CVC (central venous catheter) observations. Findings Include: 1. A policy titled, "Personal Protective Equipment," published 2/14/2018 Version 5, was provided by the Clinical Manager on 9/27/2021 at 2:25 p.m. The policy indicated, but was not limited to, "Remove gloves and wash hands after each patient contact, and after exposure to blood and body fluids. If hands are not visibly soiled, use of a waterless antiseptic hand rub is acceptable" ... "If gloves are visibly contaminated, change gloves. Wash hands before putting on new gloves, touching any surfaces and before performing other activities." 2. An observation was completed on the treatment floor of a CVC being terminated for Patient 3 by Employee E on 9/27/2021 at 9:50 a.m. Observed Employee E pull Patient 3's mask up over the nose with a gloved hand. Patient 3 was standing to obtain post treatment weight. The clean field placed under his CVC was slipping so Employee E then grabbed the clean field and adjusted it back	V 0113	On October 15, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: ·Personal Protective Equipment Emphasis was placed on: · Remove gloves and wash hands after each patient contact, and after exposure to blood and body fluids. · Hand hygiene may be performed by hand washing or using an alcohol based hand rub. · If hands are not visibly soiled, use of a waterless antiseptic hand rub is acceptable. · If gloves are visibly contaminated, change gloves and wash hands before putting on new gloves, touching any surfaces and before performing other activities. · A contaminated clean field under the Central Venous Catheter (CVC) must be changed immediately. Effective October 16, 2021, the Clinic Manager or designee will conduct infection control audits	10/30/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	in place contaminating the clean field. Employee E then continued with the termination of Patient 3's treatment with no additional glove change or hand hygiene. The clean field was not replaced when contaminated. 3. An interview with the Administrator, the Clinic Manager, the Home Dialysis Nurse Supervisor, Employee G, and Employee N was completed on 9/27/2021 at 12:18 p.m. All were advised of the observation noted above with the absence of hand hygiene and glove change, as well as lack of changing the contaminated clean field. The clinical manager confirmed that this was a breach in infection control practices and agreed to pull their policy on infection control for review.		five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on changing gloves, practicing hand hygiene, and changing the CVC clean field per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI 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 QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. 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	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
			of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	
V 0115 Bldg. 00	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. Based on observation, record review, and interview, the facility failed to ensure that staff were wearing appropriate PPE (personal protective equipment) preventing cross contamination of blood borne pathogens in 1 of 1 home hemodialysis observations. Findings Include: 1. A policy titled, "Personal Protective Equipment," published 2/14/2018 Version 5, was provided by the Clinical Manager on 9/27/2021 at 2:25 p.m. The policy indicated, but was not limited to, "Personal protective equipment such as a full face shield or mask and protective eyewear with full side shield, fluid-resistant gowns and gloves will be worn to protect and prevent employees from blood or other potentially infection materials to pass through to or reach the employee's skin,	V 0115	On October 15, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: ·Personal Protective Equipment Emphasis was placed on: ·Personal Protective Equipment (PPE) usage requirements. ·PPE such as a fluid-resistant gown and shield will be worn to protect and prevent employees from blood or other potentially infectious materials to pass through to or reach the employee's skin, eyes, mouth, other mucous membranes or work clothes when performing procedures during which spurting and spattering of blood might occur during dialysis	10/30/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	eyes, mouth, other mucous membranes, or work clothes when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood)." 2. On 9/27/2021 at 9:15 a.m., upon entering the dialysis facility from the waiting room lobby, observed through glass sliding window, Employee K cannulating (inserting dialysis needles) a patient's dialysis access to begin treatment. Employee K was not wearing a fluid-resistant gown or face shield. 3. An interview with Employee J was conducted on 9/27/2021 at 2:03 p.m. Employee J confirmed that staff should be wearing all PPE (mask, face shield, gown, and gloves) during the initiation of treatment.		needle insertion for initiation of dialysis. Effective October 16, 2021, the Clinical Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on PPE usage to promote infection control and reduce employee exposure risk to biohazardous waste. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI 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 QAI Committee is responsible to provide oversight, review findings,	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
			and take actions as appropriate. 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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	
V 0187 Bldg. 00	494.40(a) ENVIRONMENT-SCHEMATIC DIAGRAMS/LABELS 8 Environment: schematic diagrams/labels Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction. Additionally, piping should be labeled to indicate the contents of the pipe and direction of flow. If water system manufacturers have not done so, users should label major water system components in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range. Based on observation and interview, the facility failed to post water flow directional arrows in the water room for 1 of 1 facilities observed. Findings Include:	V 0187	On October 15, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: ·Equipment Installation, Operation, Maintenance, Repair,	10/30/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	1. An observation on 9/27/2021 at 11:45 a.m. with Employee M and Employee N present during the flash tour in the water room. When discussing the flow of water upon entering the facility it was noted that there was a partial lack of water flow directional arrows posted on the plumbing near the city feed supply. 2. An interview was completed with Employee N on 9/27/2021 at 1:41 p.m. Agreed that the directional arrows located in the water room were not in place due to a recent repair. Requested a policy regarding labeling of water room. 3. An interview was completed with Employee N on 9/27/2021 at 3:50 p.m. Employee N indicated that there was no policy on labelling of the water flow in the water room that he could find. Indicated that he would be reaching out to upper management for assistance in locating a policy regarding this and would provide if found. No further documentation was provided.		and Disposal ·Environment - Schematic Diagrams & Labels CfC Emphasis was placed on: · Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction. · Piping should be labeled to indicate the contents of the pipe and direction of flow. · Water flow directional arrows will be replaced immediately after repairs. · All equipment will be installed, operated, maintained, and repaired in accordance with manufacturer's instructions for use. Immediate actions taken on September 27, 2021, the Area Technical Operations Manager installed directional arrows on the repaired water room piping. Effective October 16, 2021, the Clinical Manager or designee will conduct water room audits daily for one week, then once weekly for two weeks, then once every two weeks for one month utilizing the Physical Environment Audit Tool. The focus will be on appropriate labeling in the water room and prompt replacement when indicated. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI)	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
			calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI 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 QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. 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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	
V 0455 Bldg. 00	494.70(a)(4) PR-PRIVACY & CONFIDENTIALITY-RECORDS The patient has the right to-			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	(4) Privacy and confidentiality in personal medical records; Based on observation, record review, and interview, the facility failed to protect privacy and confidentiality of patient's medical records from view on 1 of 4 days surveyed, (9/27/2021). This had the potential to affect all 21 in-center patients. Findings include: 1. A policy titled, "Patient Rights and Responsibilities," published 4/4/2012 Version 2, was provided by the Clinical Manager on 9/27/2021 at 2:55 p.m. The policy indicated, but was not limited to, "The patient has the right to" ... "4. Privacy and confidentiality in personal medical records." 2. During an observation on the treatment floor during the flash tour on 9/27/2021 at 11:40 a.m., surveyor observed the COVID-19 patient questionnaire binder laying open with patient information in full view at the nurse's station. This was located just inside the treatment floor near the entrance/exit door between the treatment floor and patient lobby. This included patient names along with medical information regarding answers for the screening of COVID-19 symptoms. 3. An interview with the Administrator was completed on 9/27/2021 at 12:18 p.m. The administrator agreed that the binder with patient information should be closed to maintain patient confidentiality.	V 0455	On October 15, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Patient Rights and Responsibilities Emphasis was placed on: · Ensuring patient's right to privacy and confidentiality in personal medical records. · COVID-19 Screening Forms will be placed in a secure area to maintain patient privacy. Effective October 16, 2021, the Clinical Manager or designee will conduct patient privacy audits daily for one week, then once weekly for two weeks, then once every two weeks for one month utilizing the Physical Environment Monitoring Tool. The focus will be on ensuring patient confidentiality is maintained per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of	10/30/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
			Correction prior to presenting to the QAI 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 QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. 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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	
V 0543 Bldg. 00	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on observation, record review, and interview, the facility failed to ensure that blood pressures were checked every 30 minutes on 1 of 4 hemodialysis patients reviewed. (Patient 4)	V 0543	On October 15, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: ·Nursing Supervision and	10/30/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	Findings Include: 1. A policy titled, "Nursing Supervision and Delegation," published on 11/2/2020 Version 4, was provided by the Clinic Manager on 9/29/2021 at 11:23 a.m. The policy indicated, but was not limited to, "Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulation." 2. The treatment sheet for Patient 4 was reviewed on 9/28/2021 and indicated the following: A Blood pressure and pulse were obtained on 9/15/2021 at 1:34 p.m. with a subsequent reading at 2:28 p.m., indicated a greater than 30-minute blood pressure and pulse check during treatment. A Blood pressure and pulse were obtained on 9/20/2021 at 1:39 p.m. with a subsequent reading at 3:02 p.m., indicating a greater than 30-minute blood pressure and pulse check during treatment. 3. During an interview with the Clinic Manager on 9/29/2021 at 1:08 p.m., agreed that the blood pressure checks were completed greater than 30 minutes apart. No further documentation was provided.		Delegation Emphasis was placed on: · Ensuring blood pressure and pulse rate are monitored every 30 minutes or more as needed but not to exceed 45 minutes or per state regulation during hemodialysis treatment. Effective October 16, 2021, the Clinical Manager or designee will conduct hemodialysis treatment sheet audits on a minimum of ten patient records daily for two weeks, then weekly for four weeks, then every two weeks for one month utilizing the Patient Treatment Sheet Monitoring Tool. The focus will be on monitoring and documentation of vital signs per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
			resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. 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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	
V 0544 Bldg. 00	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. Based on observation, record review, and interview, the facility failed to follow physician's orders regarding BFR's (blood flow rate) and DFR's (dialysate flow rates) in 3 of 4 incenter hemodialysis patients reviewed. (Patient 2, 3, and 5) Findings Include: 1. A policy titled, "Nursing Supervision and Delegation," published on 11/2/2020 Version 4,	V 0544	On October 15, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: ·Nursing Supervision and Delegation Emphasis was placed on: · The registered nurse must evaluate each patient, review patient treatment prescription to	10/30/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	was provided by the Clinic Manager on 9/27/2021 at 11:23 a.m. The policy indicated, but was not limited to, "The registered nurse must evaluate each patient preferably within an hour or according to state requirements to: Review patient treatment prescription and equipment parameters to verify correct settings, and if dialysis prescription is being followed" ... "Check prescribed blood flow is being achieved or reason is documented in medical record if unable to meet prescribed blood flow" ... "Check dialysate flow rate setting is correct, and the prescribed flow is being delivered." 2. The medical record for Patient 2 was reviewed on 9/28/2021 for treatment days 9/13/2021-9/24/2021. The prescribed BFR was 400. The prescribed DFR was Auto 1.5. The treatment sheet dated 9/13/2021 indicated a BFR of 300 during treatment. The treatment sheet dated 9/15/2021 indicated a BFR of 300 during treatment. The treatment sheet dated 9/17/2021 indicated a BFR of 300 during treatment and the DFR of 600, not 1.5 times the BFR. The treatment sheet dated 9/20/2021 indicated a BFR of 300 during treatment and a DFR of 800, not 1.5 times the BFR. The treatment sheet dated 9/24/2021 indicated a BFR of 375 during treatment (exception the first hour). 3. The medical record for Patient 3 was reviewed on 9/28/2021 for treatment days 9/15/2021-9/27/2021. The prescribed BFR was 400.		verify setting and if dialysis prescription is being followed. · Verifying machine settings and measurements to match the dialysis prescription. · Verifying prescribed blood flow rate (BFR) and Dialysate Flow Rate (DFR) are being achieved or reason is documented in medical record if unable to meet the dialysis prescription. · Verifying the following elements by two staff members prior to treatment initiation: prescribed dialyzer, BFR/DFR, and prescribed dialysate composition per hemodialysis treatment physician's order. Effective October 16, 2021, the Clinical Manager or designee will conduct hemodialysis treatment sheet audits on a minimum of ten patient records daily for two weeks, then weekly for four weeks, then every two weeks for one month utilizing the Patient Treatment Sheet Monitoring Tool. The focus will be on documentation of BFR/DFR achieved as prescribed or MD notification when indicated. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	The prescribed DFR was Auto 1.5. The treatment sheet dated 9/17/2021 indicated a DFR of 800 when BFR was at 400. The treatment sheet dated 9/20/2021 indicated a BFR of 375 and 380 the last hour and 15 minutes of treatment. The treatment sheet dated 9/22/2021 indicated a BFR of 300, 375, and 340 during treatment. The treatment sheet dated 9/27/2021 indicated a BFR of 400 at 5:43 a.m. (start of treatment) with note stating BFR decreased to 350 due to arterial pressure, RN (registered nurse) aware. At 6:06 a.m. BFR 325 with no documentation provided. At 7:03 p.m. BFR at 300 with no documentation provided. At 9:02 a.m. BFR at 275 with no documentation. At 9:33 a.m. BFR at 250 with no documentation. 4. The medical record for Patient 5 was reviewed on 9/28/2021 for treatment days 9/13/2021-9/27/2021. The prescribed BFR was 400. The prescribed DFR was 800. The treatment sheet dated 9/13/2021 indicated a DFR of 600 during treatment. The treatment sheet dated 9/15/2021 indicated a BFR of 350 during treatment. The treatment sheet dated 9/17/2021 indicated a DFR of 600 during treatment. The treatment sheet dated 9/24/2021 indicated a BFR of 370 and a DFR of 600 during treatment. 5. During an observation on the treatment floor on 9/29/2021 at 11:58 a.m. 5 dialysis machines		at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI 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 QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. 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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	settings were verified. 1 of 5 machines were set incorrectly. Patient 2 ordered DFR was running at 2.0 Auto. The prescribed DFR ordered was 1.5 Auto. 6. An interview with the Clinical Manager on 9/20/2021 at 11:58 a.m. the observed wrong BFR and DFR was discussed. Advised of this finding frequently throughout the medical record reviews as well as today with machine setting verifications. Agreed that any changes in the prescribed orders needs to be documented. Unable to voice exactly why orders were not being followed. Provided possible explanation that these were not followed due to arterial pressures, OLC (on-line clearances-light being yellow and attempting to obtain better adequacy), or possible lab draw days to obtain better Kt/v lab values. No further documentation was provided.			
V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on observation, record review, and interview, the medical director failed to ensure that policies were being followed regarding expired supplies and medication securement in 1 of 1 facilities observed. Findings Include: 1. A policy titled, "Storage of Supplies,"	V 0715	On October 15, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: ·Medication Preparation and Administration ·Storage of Supplies ·Emergency Equipment and Supplies	10/30/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	published 4/5/2021 Version 2, was provided by the Clinical Manager on 9/27/2021 at 2:55 p.m. The policy indicated, but was not limited to, "Proper storage conditions are necessary to provide a safe environment and to ensure supplies are not expired, contaminated, or damaged" ... "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." 2. A policy titled, "Emergency Equipment and Supplies," published 7/6/2020 Version 5, was provided by Employee J on 9/27/2021 at 3:25 p.m. The policy indicated, but was not limited to, "The emergency cart must be: Locked when not in use." 3. A policy titled, "Medication Preparation and Administration," published 4/5/2021 Version 6, was provided by the Clinic Manager on 9/27/2021 at 3:05 p.m. The policy indicated, but was not limited to, "Securement: The following steps must be taken for the securement: All medications will be kept in a locked cabinet except when in use." 4. During an observation on 9/27/2021 at 11:23 a.m. during the flash tour observed 3 culture sets located in a cabinet in the lab area that were expired. Expiration dates of 6/4/2021. 5. During an observation on 9/27/2021 at 11:33 p.m. during the flash tour the surveyor observed a plastic tote located on the emergency crash cart containing medications. The yellow breakaway tag was broken and the medications were unsecured. 6. An interview with the administrator, clinical manager, Employee J, Employee N, and Employee G was completed on 9/27/2021 at 12:18 p.m. during		Emphasis was placed on: · Ensuring all policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers. · Ensure policies are being followed regarding expired supplies and medication securement. · The emergency cart must be locked when not in use. · All medications will be kept in a locked cabinet except when in use. · Ensuring supplies are immediately available for use including but not limited to blood cultures and lab supplies. Effective October 16, 2021, the Clinical Manager or designee will conduct will conduct supply and security audits daily for one week, then once weekly for two weeks, then once every two weeks for one month utilizing the Physical Environment Monitoring Tool. The focus will be on prompt removal of expired supplies, verification of locked medication cabinets and utilization of the break-away tag to secure the emergency code cart. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152626	A. BUILDING 00 B. WING	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE ELWOOD	1805 S ANDERSON ST ELWOOD, IN 46036

(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
	the entrance conference. Advised of expired blood cultures found in the lab cabinet on the treatment floor. No further documentation was provided. Advised of medication tote found on the emergency crash cart with broken yellow breakaway tag and that medications were left unsecured. Agreed that medications should be placed in cart and secured.		Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI 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 QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. 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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	