STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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 0000 Bldg. 00	This visit was a Post Condition Revisit for a Federal complaint dated February 22, 2024, of an ESRD provider. Survey dates: March 16 and 17, 2024 Census by Service Type: In-Center Hemodialysis: 88 Home Hemodialysis: 0 Home Peritoneal dialysis: 15 Total Active Census: 103 Isolation Room/Waiver: 1 During this visit, three Conditions for Coverage and sixteen standard level deficiencies were determined to be corrected, 6 standard level deficiencies were re-cited, and 2 new standard level deficiencies were cited. QR: A 1, 4/25/24	V 0000		
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, policy review, and interview, the dialysis facility failed to ensure staff completed hand hygiene according to hand hygiene policies and procedures during 1 of 2 observations of in-center hemodialysis (ICHD)	V 0113	On 5/9/24 & 5/10/24, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·Hand Hygiene version 8	06/07/2024

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Geralyn Vogel	Sr. Regulatory Manager	05/10/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	treatment floor observations (Patient Care Technicians [PCT] 1, 3, 5, 9). The findings include: 1. Policy #47664, titled "Hand Hygiene," dated 11/06/23, indicated hand hygiene should be performed before and after direct contact with patients, when entering and leaving the treatment area, and immediately after removing gloves. The policy indicated when performing hand hygiene by washing hands with soap and water, the procedure should last "40 - 60 seconds," and for hand sanitizing with alcohol based hand rub (ABHR), the procedure should last "20 - 30 seconds." 2. During an observation on the ICHD treatment floor on 4/16/24 beginning at 9:30 AM, the following was observed: a. At 9:37 AM, after caring for a patient in station 19, PCT 3 removed their gloves, performed ABHR for less than 20 seconds, donned gloves and provided care to a patient in station 20. b. At 9:41 AM, after caring for a patient in station 1, PCT 9 removed their gloves and failed to perform hand hygiene, entered the nursing station, reached into a drawer and obtained clear plastic bags with lab supplies for patients contained within. PCT 9 then entered and placed a bag of lab supplies on top of clean supplies at stations 23 and 22, respectively. c. At 9:56 AM, PCT 1 removed their gloves, performed ABHR for less than 20 seconds, donned new gloves, then provided post-treatment dressing care to a patient.		Emphasis was placed on: ·Hands will be washed with antimicrobial soap and water: ·Hands are visibly dirty or contaminated with proteinaceous material, blood, or other body fluids ·Before eating ·After using a restroom ·Anthrax or C-difficile exposure *·Duration of the entire procedure: 40-60 seconds* ·Hands will be decontaminated *using alcohol-based hand rub* or by washing hands with antimicrobial soap and water: *·Before and after direct contact with patients* ·Entering and leaving the treatment area *·Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications* *·Immediately after removing gloves* ·After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled ·After contact with inanimate objects near the patient ·When moving from a contaminated body site to a clean body site of the same patient ·After contact with the	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	d. At 10:26 AM, PCT 3 entered dialysis treamnt station 18 and provided care to Patient in station 18 without performance of hand hygiene. e. At 9:51 AM, PCT 9 was observed setting up the machine at station 23. PCT 9 went into the central supply and obtained a water strip from the container to test the machine. PCT 9 failed to remove his gloves and perform hand hygiene prior to obtaining the test strip. f. At 10:00 AM, PCT 3 was observed evaluating Patient's fistula at station #9. After evaluation of the access, PCT 3 failed to remove his/her gloves and perform hand prior to applying antiseptic and cannulating Patient's fistula. g. At 10:02 PCT 5 was observed disconnecting Patient #22 from dialysis. PCT 5 failed to ensure Patient #22 sanitized his/her hands prior to donning glove to hold his/her access site. h. At 10:07 PCT 9 was observed disconnecting Patient at station 24 from dialysis. PCT 9 failed to ensure Patient at station #24 sanitized his/her hands prior to donning glove to hold his/her access site. i. During in interview on 4/16/2024 at 10:22 AM, PCT 9 indicated hands should be sanitized when going form dirty to clean tasks, when leaving the station, and patients should sanitize their hands prior to donning gloves to hold their access site. 3. During an interview on 4/16/24 at 3:12 PM, PCT 6 indicated gloves should be changed and hand hygiene should occur when leaving a station, or going from one station to another.		dialysis wall box, concentrate, drain, or water lines, ·After contact with other objects within the patient station or treatment space *·Duration of the entire procedure: 20-30 seconds* ·Patients should perform hand hygiene if able, prior to and after each dialysis treatment. ·As needed, direct patient care staff will demonstrate how to operate the sinks, demonstrate hand washing to patients who are able to perform hand washing, and explain the risk of contamination regarding their vascular access and hands to all patients. ·Gloves must be provided to patients when performing procedures which risk exposure to blood or body fluids, such as when self-cannulating or holding access sites post treatment to achieve hemostasis. Effective 05/13/2024, Clinical Manager will conduct audits twice daily with focus on ensuring staff complete hand hygiene according to hand hygiene policy's utilizing Clinic Audit Tool for 1 week, and then daily for 1 week and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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 Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible 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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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 0122 Bldg. 00	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation and interview, the diaysis facility failed to ensure its staff maintained infection control precautions while on the treatment floor, during 1 of 2 observations of in-center hemodialysis (ICHD) treatment floor observations with Patient Care Technician (PCT) PCT 1. The findings include: During an observation on 4/16/24 at 10:15 AM, PCT 1 was observed cleaning station 14. PCT 1 cleaned the blood pressure cuff and hung it in the IV pole, The blood pressure cuff slid and was resting on the floor, PCT 1 failed to clean the blood pressure cuff after it had been on the floor. PCT 1was observed cleaning the chair and failed to recline the chair and failed to ensure the chair was left visibly wet. During an interview on 4/16/24 at 10:30 AM, PCT 1 indicated if equipment falls on the floor it should be cleaned with a wipe. She indicated when cleaning the station, the chair should be fully reclined and should be left glistening from the bleach solution.	V 0122	On 05/9/24 & 5/10/2024, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·Cleaning and Disinfecting the Dialysis Station version 14 Emphasis was placed on: ·Area including the dialysis machine, chair/bed and other reusable equipment or supplies utilized during dialysis treatment, patient training, and/or patient clinic visits. Equipment in the dialysis station may include (but is not limited to) the following: ·Dialysis machine/cycler and attachments such as IV pole, BP cuff and hand sanitizer/holder, organizer ·Chair ·Place in Trendelenburg ·Open side door panels ·Lower side tray tables ·Pureflow SL ·Individual television and remote ·The dialysis station could	06/07/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
			become contaminated with blood and other body fluids during treatment. After use, any non-disposable equipment and supplies brought into the dialysis station must be disinfected with 1:100 bleach or EPA registered disinfectant before being removed from the dialysis station ·All work surfaces shall be cleaned and disinfected with 1:100 bleach solution after completion of procedures. Make the surface glisteningly wet and let air dry unless otherwise specified by the manufacturer. Effective 05/13/2024, Clinical Manager will conduct audits twice daily with focus on ensuring staff maintain infection control precautions while on the treatment floor utilizing Clinic Audit Tool for 1 week and then daily for 1 week and then weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
			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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.	
V 0455 Bldg. 00	494.70(a)(4) PR-PRIVACY & CONFIDENTIALITY-RECORDS The patient has the right to- (4) Privacy and confidentiality in personal medical records; Based on observation and interview the dialysis	V 0455	On 05/09/24 & 5/10/2024, the Clinical Manager held a staff	06/07/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	facility failed to maintain patient clinical record confidentiality in 1 of 2 days of dialysis treatment floor observations. (Patient #37, 38). Findings include: 1. During an observation of the dialysis treatment floor on 04/16/2024, beginning at 9:30 AM, Patient #37's Against Medical Advice Signature Form was above nurse's station desk on a shelf with Patients' information visible. 2. During an observation of the dialysis treatment floor 04/16/2024, beginning at 9:30 AM, Registered Nurse 5 exited the nurse's station and left the computer screen with Patient #38's electronic medical record information open and visible from outside of the nurse's station desk. Registered Nurse 5 returned to the nurse's station desk and again left the nurse's station desk and went to dialysis station 7, then retrieved a snack for the patient at station 7; during this time, the nurse's station computer screen with Patient #38's electronic medical record information was open and visible from outside of the nurse's station desk. Registered Nurse 5 then returned to the nurse's desk computer. 3. During an interview on 04/16/2024, at 10:44 AM, Registered Nurse 5 indicated patient clinical record information confidentiality should be maintained by ensuring patient's paper documentation was turned over so no patient information was visible and the computer with electronic medical record information should be logged off or locked when leaving the computer, unless there was an emergency situation that could not allow for locking of the computer. Registered Nurse 5 indicated she was not provided patient confidentiality training and		meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·HIPAA Privacy Policy and Procedures COR-ISO-024 ·Medical Record Documentation Standards version 4 ·Patient Rights and Responsibilities List version 3 ·Patient Rights and Responsibilities Procedure version 2 Emphasis was placed on: ·Paper PHI should be secured, and access should be limited based on job duties. ·Paper PHI should be properly discarded in a container marked for shredding. ·Storage of electronic PHI is limited to those who require access to perform their job duties. ·All patients' medical records will be maintained in accordance with accepted professional standards and practices, and in compliance with state law. ·Patients have the right to: ·Information that is easy to understand. ·Care that is respectful. ·Help make decisions about your care. ·Privacy and Confidentiality ·Privacy and confidentiality in all aspects of treatment. This includes the right to privately discuss your condition as well as the right to privacy	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	worked once per week at the facility.		during activities that may require the exposure of body parts while in the dialysis facility. Privacy screens, curtains, or blankets that do not cover your face or access may be used to provide privacy. ·Privacy and confidentiality in your personal medical records ·Clear information about facility policies Effective 05/13/2024, Clinical Manager will conduct audits twice daily with focus on ensuring patient clinical record confidentiality is maintained utilizing Clinic Audit Tool for 1 week and then daily for 1 week followed by weekly for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the 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	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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 Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.	
V 0516 Bldg. 00	494.80(b)(1) PA-FREQUENCY-INITIAL-30 DAYS/13 TX An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session. Based on record review and interview, the Interdisciplinary Team (IDT) failed to ensure the initial interdisciplinary comprehensive assessment was completed for 1 of 2 newly admitted patients who received dialysis treatments for greater than	V 0516	On 05/09/24 & 5/10/2024, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·Comprehensive Interdisciplinary	06/07/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	30 days, and received at least 13 hemodialysis sessions (Patient #34). The findings include: 1. Patient #34's clinical record included a hospital document dated 02/16/24, which evidenced Patient had a heart transplant in 2020, was deemed dialysis dependent during this hospitalization (2/01/24 - 2/13/24), and a central venous catheter (CVC) (a tube inserted into a large vein, usually under the right collarbone, for administration of dialysis treatments) was placed on 02/06/24. 2. As of 4/17/24, the clinical record failed to evidence all members of the IDT completed a discipline-specific initial comprehensive assessment to assure all required elements of the comprehensive assessment were addressed. The record evidenced: A. An admission and first treatment visit note dated of 02/15/24. B. Treatment notes dated 02/16/24, 2/19/24, 2/21/24, and 2/26/24. C. A hospitalization occurred from 02/26/24 - 3/01/24. A hospital document evidenced the patient was hospitalized on 02/26/24, after complaints of shortness of breath and chest pain during their dialysis treatment. D. Treatment records dated 3/04/24, 3/06/24 and 3/08/24. E. Hospitalization occurred from 3/11/24 to 4/02/24. F. Treatment record notes dated 4/03/24, 4/05/24, 4/08/24, 4/10/24, and 4/12/24, (4/12/24 being the 13th dialysis treatment session), and 4/15/24. G. Nurse Practitioner (NP) 1's provider visit note, dated 4/03/24, indicated Patient was status post hospitalization (3/11/24 - 4/02/24) and now required a dobutamine drip (an intervenous [IV]		Assessment and Plan of Care version 6 Emphasis was placed on: ·An initial comprehensive interdisciplinary assessment (CIA) and plan of care (POC) must be conducted on all patients new to dialysis within the later of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. Patients changing modality are classified as new patients and must have comprehensive interdisciplinary assessments and plans of care completed with the same frequency as patients new to dialysis. ·The timeline for both the completion of the initial comprehensive assessment and the beginning of implementation of the initial patient plan of care is the latter of 30 days from the date of admission or 13 hemodialysis treatments at the facility. ·Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments. Effective 05/13/2024, Clinical Manager will conduct monthly audits of the electronic Plan of Care to ensure that all new patients, i.e. all admissions to the dialysis facility, will have an initial CIA completed by all members of	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	drug given to treat severe heart failure) and was unstable. 3. During an interview on 4/17/24 at 9:11 AM, the Administrator indicated Patient #34 didn't have a POC yet because of the lengthy hospital stay, the IDT meeting to finalize the initial POC was scheduled for 4/29/24, and all components of the inderdisciplinary assessments would be done, reviewed, and used to create the POC at that time. During an interview on 4/17/24 at 11:40 AM, the Clinical Manager indicated the Medical Director rounded monthly at the facility; the patient was in the hospital the last time the Medical Director rounded, therefore Patient was not seen. The Medical Director was next scheduled to be in the clinic on 4/29/24 and the comprhensive assessment and care plan was scheduled to be completed at that time.		the IDT, as well as a POC completed within 13 treatments or 30 calendar days from the first dialysis session. Monitoring for continued compliance will be done monthly with findings reported in QAI and documented in the meeting minutes in eQUIP. 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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.	
V 0520 Bldg. 00	494.80(d)(2) PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted- At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis. Based on record review and interview, the Interdisciplinary Team (IDT) failed to ensure a comprehesive reassessment was completed for 1 of 2 newly admitted patients who received outpatient hemodialysis sessions for greater than 30 days, and was classified as "unstable" (Patient #34). The findings include: Patient #34's clinical record included a hospital document dated 2/16/24, which evidenced the patient had a heart transplant in 2020, had frequent re-hospitalizations due to complex co-morbidities, was deemed dialysis dependent	V 0520	On 05/9/24 & 5/10/2024, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·Comprehensive Interdisciplinary Assessment and Plan of Care version 6 Emphasis was placed on: ·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.	06/07/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	during this hospitalization (2/01/24 - 2/13/24), a central venous catheter (CVC) (a tube inserted into a large vein, usually under the right collarbone, for administration of dialysis treatments) was placed on 2/06/24, and dialysis treatments would begin immediately. Patient #34's clinical record included but not limited to an admission and first treatment visit note dated of 2/15/24, a visit note dated 2/26/24, hospitalization 2/26/24 - 3/01/24, a visit note dated 3/08/24, and hospitalization 3/11/24 - 4/02/24. A hospital document evidenced the patient was hospitalized on 2/26/24, after complaints of shortness of breath and chest pain during dialysis treatment. An undated document received on 4/16/24, titled "Unstable Patients", indicated Patient #34 was listed as unstable in March (2024), and was not listed as unstable in February (2024). Nurse Practitioner (NP) 1's provider note dated 4/03/24 indicated the patient was status post hospitalization (3/11/24 - 4/02/24), now required a dobutamine drip (an intravenous [IV] drug), given to treat severe heart failure, and was unstable. As of 4/17/24, the clinical record failed to evidence a completed initial comprehensive assessment or reassessment. During an interview on 4/17/24 at 9:11 AM, the Administrator indicated Patient #34 didn't have a POC yet because of the lengthy hospital stay, the IDT meeting to finalize the initial POC was scheduled for 4/29/24, and all components of the inderdisciplinary assessments would be done, reviewed, and used to create the POC at that time.		·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 examples of unstable criteria: ·Extended or Frequent hospitalizations: ·Hospitalization of more than 15 days with discharge occurring within the last 30 days ·More than 3 admissions in the last 30 days ·Marked deterioration in health status – IDT to identify and document the specific reasons. (i.e. requiring dobutamine drip) Effective 05/13/2024, the Clinical Manager will conduct monthly audits of the electronic Plan of Care for a list of all current patients within the dialysis facility as well as their stability status. The Clinical Manager will be responsible for ensuring all unstable patients have a monthly CIA completed by all members of the IDT as well as a completed POC. Monitoring for continued compliance will be done monthly with findings reported in QAI and documented in the meeting minutes in eQUIP.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	During an interview on 4/17/24 at 11:40 AM, the Clinical Manager indicated the Medical Director rounded monthly at the facility, the patient was in the hospital the last time the Medical Director rounded, so the patient was not seen, and the Medical Director would be here next on 4/29/24.		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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.	
V 0543	494.90(a)(1) POC-MANAGE VOLUME STATUS			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
Bldg. 00	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 record review and interview, the dialysis facility failed to ensure the physician was notified when an in-center hemodialysis (ICHD) patient was below their Estimated Dry Weight (EDW) prior to treatment, when an ICHD patient's post-treatment weight was greater than/less than 1 kilogram of the ordered EDW, ensured staff followed facility policies specific to the treatment of orthostatic hypotension, or ensure the patient was assessed and/or monitored per policy, for 1 of 2 newly admitted patients who received ICHD sessions for greater than 30 days (Patient #34). The findings include: 1. A policy titled "Volume Management in ESRD [End Stage Renal Disease] Patients on Hemodialysis," dated 9/7/2021, indicated if any of the following patient clinical conditions occurred, refer to the volume algorithm, and if applicable, consult with the physician for appropriate fluid interventions: pre-treatment weight less than or equal to EDW, EDW order should be updated post-treatment adjustments and patient fluid status, and the clinical care team must be diligent in determining the EDW and routinely assess and adjust this metric, and the EDW order should be updated post-treatment to reflect treatment adjustments and patient fluid status. 2. A policy titled "Patient Assessment and Monitoring," dated 5/1/2023, indicated if staff noted any changes or abnormal findings in the	V 0543	On 5/9/24 & 5/10/24, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·Volume Management in ESRD Patients on Hemodialysis version 1 ·Patient Assessment and Monitoring version 4 ·Guidelines for Recognizing and Treating Orthostatic (Postural) Hypotension version 3 ·Nursing Supervision and Delegation version 6 Emphasis was placed on: ·The registered nurse must evaluate each patient *within an hour* or according to state requirements to: ·Confirm identity. ·Review the patient's condition. ·Review accuracy and completeness of treatment and patient data. ·Review patient treatment prescription and equipment parameters to verify correct settings, and if dialysis prescription is being followed. ·Confirm that the correct vascular access is being used,	06/07/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	patient's condition were observed or reported by the patient, the Registered Nurse (RN) must be informed, any abnormal finding confirmed by the RN would be reported to the attending physician ... Maintain the patient post-treatment weight and ensure the post weight is consistent with the goal set of the machine ... Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes per state regulations ... The Registered Nurse will assess/reassess post-treatment as indicated." 3. A policy titled "Guidelines for Recognizing and Treating Orthostatic (Postural) Hypotension," dated 02/07/2022, indicated orthostatic hypotension was a drop in blood pressure (BP) from sitting to standing that was equal to or great than 20 mm Hg (millimeters of mercury, the measurement of blood pressure) systolic (top number of a blood pressure reading) or 10 mm Hg diastolic (bottom number of a blood pressure reading), the RN would notify the nephrologist when orthostatic hypotension was not relieved by intervention. 4. A policy titled "Nursing Supervision and Delegation," dated 5/1/23, indicated the following task may not be delegated: assessment of each patient, preferably within one hour of treatment initiation in the clinic setting. 5. Patient #34's clinical record included a hospital document dated 2/16/24, which evidenced the patient had a heart transplant in 2020, had frequent re-hospitalizations due to complex co-morbidities, was deemed dialysis dependent during this hospitalization (2/01/24 - 2/13/24), a central venous catheter (CVC) (a tube inserted into a large vein, usually under the right collarbone, for administration of dialysis		and that the access is visible. ·Observe patient's response to treatment. ·Verify machine safety checks have been completed. ·Talk to the patient to elicit information such as changes in condition, response to treatment, new injuries, information/education needs or complaints, satisfaction with care. ·Fluid balance is an integral component of the HD treatment to prevent patient hyper- or hypovolemia both of which have been demonstrated to influence mortality and cardiovascular complications in ESRD patients on HD. *Registered nurse should complete a fluid assessment on all ESRD patients receiving HD treatments. Assessment should evaluate patients for hypo- and hypervolemia.* ·At a minimum, fluid assessment will include review of the following clinical indicators: o ·EDW ·Pre/Post Weight ·Post Weight comparison to EDW. *·Pre/Post Blood Pressure* *·Orthostatic Hypotension: A drop in blood pressure from sitting to standing that is equal to or greater than 20 mm Hg systolic or 10 mm Hg diastolic.* ·Lowest Intradialytic Blood Pressure ·Signs/symptoms of fluid	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	treatments) was placed on 2/06/24, dialysis treatments began immediately, and discharge weight was 90.1 kilograms (kg). A physician order report indicated the dialysis facility ordered EDW on 02/15/24 at 93 kg. Nurse Practitioner (NP) 1's provider note dated 02/15/24, indicated on 02/15/24, the Patient's EDW was 93 kg, pre-treatment weight was 92.5 kg, post-treatment weight was 92.2 kg (first ICHD dialysis session), and both were below ordered EDW. NP 1's provider note dated 02/23/24, indicated the Patient's EDW was 93 kg (effective 2/15/24); Patient experienced stabbing pain to the upper abdomen during treatment on 02/23/24. On 02/16/24, the pre-treatment weight was 92.5 kg (less than ordered EDW). On 02/21/24, the pre-treatment weight was 95.0 kg, and post-treatment weight was 95.1 kg (post-treatment 2.1 kg over ordered EDW). Pre-treatment sitting BP was 119/87, and standing was 96/85, which indicated orthostatic hypotension. A hospital document dated 3/01/24 indicated Patient presented to the hospital on 02/26/24 for complaints of shortness of breath and chest pain during dialysis that day. The practitioner's review of Patient's personal detailed dialysis logs indicated there was very little fluid removed from Patient on the days he/she attended outpatient dialysis. During the hospitalization (02/26/24 - 3/01/24), adequate amounts of fluid were removed during each inpatient session, and the EDW was roughly around 90 kg. Patient's admission weight		overload ·Physical examination including lung assessment, cardiovascular (i.e. heart sounds) and peripheral vascular assessment (edema) *·Prior to discharge, the RN must review the treatment record to:* *·Confirm patent is stable for discharge.* ·Identify any process that could have resulted in the patient experiencing a safety event or near miss. *·The record must be reviewed for*: ·Slow/fast/irregular heart rate *·Low or high blood pressures* *·Whether patient is achieving dry weight and identifying reason for patient not achieving dry weight* ·Heart rate 100 addressed by the registered nurse with documentation present. Blood pressures < 100 systolic or greater than 180 systolic addressed by the registered nurse with or documentation present. ·Reported fall, and if heparin was held and MD notified. ·Correct dialysate prescription was delivered. *·The RN will notify the patient's physician/physician extender of any abnormal findings, if necessary, based on clinical judgment for additional instruction.* Effective 05/13/2024, Clinical	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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 94.1 kg, and discharge weight was 92.0 kg. The clinical record failed to evidence the dialysis clinic adjusted Patient's EDW post-hospital, discharged date 3/01/24. On 3/04/24, pre-treatment weight was 93.8 kg, and post-treatment weight was 94.0 kg. On 3/06/24, pre-treatment weight was 96.6 kg, and post-treatment weight was 95.1 kg. The clinical record evidenced the patient was hospitalized again for heart failure exacerbation from 3/11/24 - 4/02/24. NP 1's provider note dated 4/03/24 indicated the patient was post-hospitalization, now required intravenous (IV) dobutamine (a medication to treat severe heart failure), and ordered EDW was 93.0 kg. A dialysis treatment flowsheet dated 4/03/24 indicated ordered EDW was 93.0 kg, pre-treatment weight was 96.3 kg, and post-treatment weight was 95.8 kg. A dialysis treatment flowsheet dated 4/05/24 indicated the patient began treatment at 11:47 AM, and the RN assessed the patient at 1:23 PM (greater than 1 hour after treatment initiation). A dialysis treatment flowsheet dated 4/08/24 indicated ordered EDW was 93.0 kg, pre-treatment weight was 93.0 kg, and post-treatment weight was 90.3 kg. The clinical record evidenced the ordered EDW was changed to 90.5 kg, and treatment duration time was increased to 3 hours and 45 minutes on		Manager will conduct 10 treatment sheets daily, alternating shifts, with focus on ensuring the physician is notified when the ICHD patient is below their EDW prior to treatment or when a post treatment weight is greater than/less than 1 kilogram of the ordered EDW, as well as, ensuring patients are assessed within one hour of initiation of the dialysis treatment and policies specific to recognizing and treatment of orthostatic hypotension are followed utilizing Treatment Sheet Audit Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible 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
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	4/10/24. A dialysis treatment flowsheet dated 4/10/24 indicated dialysis prescription was treatment duration 3 hours and 30 minutes, treatment was initiated at 10:03 AM, and discontinued at 2:06 PM. Post-treatment sitting BP was 134/99, and standing BP was 111/73 (indicative of orthostatic hypotension). PCT 5 failed to notify the RN. A diaysis treatment flowsheet dated 4/12/24 indicated EDW was 90.5 kg, pre-treatment weight was 90.5 kg, and post-treatment weight was 88.8 kg. A diaysis treatment flowsheet dated 4/15/24 indicated EDW was 90.5 kg, pre-treatment weight was 89.5 kg, and post-treatment weight was 87.8 kg. During an interview on 4/17/24 at 1:30 PM, the Administrator indicated staff shouldn't pull fluid during treatment if the patient was below EDW, they should just clean the blood and notify the physician, and should have notified the physician when the patient was 1 kg above or below EDW post-treatment.		resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.	
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 record review and interview, the dialysis facility failed to ensure patient dialysis prescriptions orders were adhered to in order to	V 0544	On 5/9/24 & 5/10/24, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff	06/07/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	achieve and sustain the prescribed dose of dialysis to meet the adequacy of dialysis in 2 of 5 patient treatment records reviewed (Patient #20, 29). Findings include: 1. A current order report for Patient #29 indicated the patient's prescribed DFR (dialysate flow rate) was 500 milliliters per minute. The treatment flowsheet on 04/05/2024, from 10:50 AM to 2:09 PM, indicated the patient's DFR was at 800 milliliters per minute. The review failed to evidence why the patient did not receive the prescribed dialysate flow rate. The treatment flowsheet on 04/15/2024, from 11:05 AM to 2:15 PM, indicated the patient's DFR was at 800 milliliters per minute. The review failed to evidence why the patient did not receive the prescribed dialysate flow rate. During an interview on 04/17/2024, at 11:42 AM, Patient Care Technician 3 indicated the patient should receive the prescribed hemodialysis orders. During an interview on 04/17/2024, at 12:30 PM, the Clinical Manager indicated the patient did not receive the correct DFR ordered on 04/05/2024 and 04/15/2024 and should have been at 500 milliliters per minute. 2. A clinical record review for Patient #20 included a review of the dialysis treatment sheets from 3//28/24 - 4/14/24 and evidenced the following: The flowsheets dated 4/2/24 and 4/9/2024 indicated Patient #20's prescribed dialysate flow rate (DFR) was autoflow 1.5 which would have		on policies: ·Patient Assessment and Monitoring version 4 Emphasis was placed on: ·Document machine parameters and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. ·Check machine settings and measurements: ·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. Effective 05/13/2024, Clinical Manager will conduct 10 treatment sheets daily, alternating shifts, with focus on ensuring the blood flow rate and dialysate flow rate is achieved and maintained throughout the dialysis treatment or justification documented utilizing Treatment Sheet Audit Tool for 2 weeks and then will complete weekly treatment audits on 10% of completed treatments for an additional 2 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. The Medical Director will review	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	been 600 milliliters per minute (ml/min). During treatment, Patient #20's documented DFR was 800 ml/min. The flowsheets failed to evidence documentation of why Patient did not receive the prescribed DFR. During an interview on 4/17/2024 at 11:35 AM, the clinical manager indicated she was not sure why the DFR was not as prescribed. She indicated the machine should have calculated the autoflow 1.5 as 1.5 times the BFR. She indicated the machine could have been at the wrong rate, but she would get with the Bio-Med technician to check to see why the treatment was not run at the correct rate.		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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.	
V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must-			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	(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 adhere to a facility policy, for 1 of 1 patient who's electronic medical record (EMR) was reviewed (Patient #34), which could affect all patients' care and safety, who were treated at the dialysis facility. The findings include: A "Physician Order Documentation" policy, #46933, dated 7/03/23, indicated physician orders must be signed by the physician at the time of the physician's next facility visit, must be signed within 30 days, and if the ordering physician was present on the unit, he/she should write/enter the order directly. The facility's EMR was reviewed for Patient #34 on 4/17/24, at 12:00 PM, with the Clinical Manager and Administrator. The Clinical Manager drove the EMR, hovered over various orders, and the orders failed to evidence they were reviewed, approved, or electronically signed/authenticated by the Medical Director. The Clinical Manager and Administrator both indicated the EMR did not evidence the orders were signed, or included the actual times the orders were received by facility staff. Review of an "Orders To Be Signed" report, dated 4/17/24, evidenced 193 pages of physician orders for multiple patients, all of which remained	V 0715	On 05/13/2024, the Clinical Manager met with the Medical Director to review and reinforce the expectations and responsibilities of the Medical Director, as a physician on policies: ·Physician Order Documentation version 6 ·Addressing Unsigned Provider Orders version 1 Emphasis was placed on: ·All medications, laboratory tests and treatments a patient receives require an electronic order *signed by the physician*, nurse practitioner, or physician assistant (in states where allowed). *·A Provider's signature authenticates an order. Providers who are members or affiliated members of the Medical Staff of any Facility are required to sign orders in a timely manner* as set forth in: ·federal and state law ·applicable FMCNA, Company and/or Facility policies ·applicable Medical Staff Bylaws or Professional Staff Bylaws. ·Fresenius Medical Care	06/07/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
	unsigned by the physician(s). Pages 43-49 included but not limited to 96 unsigned orders for Patient #34, for date range 2/15/24 (first dialysis treatment/admission) to 4/10/24. During an interview on 4/17/24 at 11:04 AM, the Administrator indicated she spoke to the Medical Director, and the Medical Director saw Patient #34 earlier this month and indicated he/she did not document the visit. When asked, the Administrator could not recall the last time the Medical Director was on site at the facility to assess patients. Upon survey exit, no further information was provided. During an interview on 4/17/24 at 11:40 AM, the Clinical Director indicated the Medical Director came to the facility monthly, and the last time was during Patient #34's hospitalization (3/11/24 - 4/02/24). During an interview on 4/17/24 at 12:10 PM, The Administrator indicated the Medical Director just now signed all 193 pages of orders, the system they used allowed the physician to just click one button and all orders would be automatically signed.		Holdings, Inc. d/b/a Fresenius Medical Care North America (“FMCNA”) on behalf of its affiliates and subsidiaries adopts this Policy to promote: · quality patient care ·compliance with applicable federal and state law and third-party payor requirements; and ·consistent, fair treatment of physicians and advanced practitioners (collectively, “Providers”) who practice at any outpatient dialysis center (“Facility”) that is owned or operated by any of FMCNA’s direct or indirect affiliates or subsidiaries (each a “Company”). ·A progressive review process will be used by the Company if a Provider fails to timely sign medical orders. The steps that will be taken by the Company include, but are not limited to: · ·ongoing review and monitoring of unsigned orders ·notification to the Provider of unsigned orders, and warnings as to the consequences of the continued failure to sign orders. ·notification to the Provider of the automatic relinquishment and/or resignation by the Provider of the Provider’s admitting privileges and clinical privileges, as applicable, for failure to sign orders in the time frames set forth. ·At least monthly, the Operations team (e.g., RVP, DO,	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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
			CM) shall review the Orders to Be Signed report available in eCC reports. Effective 05/14/2024, the Clinical Manager will conduct a weekly review of the Orders to Be Signed report with a focus on those orders which are greater than 30 days for 2 weeks and then will continue monthly. If a provider has one or more orders that are unsigned for longer than 30 days the provider will be notified in writing that the unsigned orders must be signed and if remain unsigned, admitting privileges will automatically be relinquished. The Operations team (RVP, DO, CM) is responsible for implementing and following the Addressing Unsigned Provider Orders policy. Unsigned orders will be reviewed monthly in QAI with documentation of compliance noted in the meeting minutes in eQUIP. 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
	152501	A. BUILDING 00 B. WING	04/17/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

(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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic.	