

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

PRINTED: 09/03/2021

FORM APPROVED

OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152605	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 08/10/2021
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NAME OF PROVIDER OR SUPPLIER BALL DIALYSIS AT FOREST RIDGE	STREET ADDRESS, CITY, STATE, ZIP COD 101 EMERSON AVE NEW CASTLE, IN 47362
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(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	<p>An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62.</p> <p>Survey Dates: August 4th, 5th, 6th, 9th, and 10th of 2021</p> <p>Facility Number: 010644</p> <p>Census: 42 Incenter Hemodialysis 2 Peritoneal Dialysis 1 Transient Hemodialysis</p> <p>At this Emergency Preparedness survey, Ball Dialysis At Forest Ridge, was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.</p> <p>QR completed 8/17/2021 A4</p>	E 0000		
V 0000 Bldg. 00	<p>This visit was for a federal ESRD (Core) recertification survey, modality addition, 2 complaints, and a COVID-19 infection control survey.</p> <p>Complaint IN00346060 unsubstantiated due to lack of evidence Complain IN00341418 unsubstantiated due to lack of evidence</p>	V 0000		

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

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosed days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V 0403 Bldg. 00	<p>Survey Dates: August 4th, 5th, 6th, 9th, and 10th of 2021</p> <p>Facility Number: 010644</p> <p>Census: 42 Incenter Hemodialysis 2 Peritoneal Dialysis 1 Transient Hemodialysis</p> <p>494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.</p> <p>Based on observation and interview, the facility failed to ensure dialysis equipment, blood pressure cuffs/cords, were maintained to provide safe and adequate care.</p> <p>Findings Include:</p> <p>During an observation on 8/4/2021 at 10:18 a.m., during the flash tour, a patient in station 13 was standing to obtain a blood pressure post dialysis. This process took several minutes to obtain due to several failed attempts for reading to be obtained.</p> <p>During an interview on 8/4/2021 at 10:18 a.m. with a patient in station 13, the patient stated that she had advised staff several times about difficulty obtaining blood pressures and the need to obtain new blood pressure cuffs and cords. Showed the blood pressure cord to surveyor and stated that it</p>	V 0403	<p>On August 20, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <ul style="list-style-type: none"> · Equipment Installation, Operation, Maintenance, Repair, and Disposal <p>Education emphasis was placed on:</p> <ul style="list-style-type: none"> · Ensure dialysis equipment, blood pressure cuffs/cords, are maintained to provide safe and adequate care. · Maintaining a program to ensure that all equipment are maintained and operated in accordance with the manufacturer's recommendations. Effective August 23, 2021, the Clinical Manager or designee will 	09/09/2021

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	was dry rotted from continuous disinfection used on them daily. Stated despite the multiple requests this problem has not been resolved.		<p>conduct hemodialysis machine equipment audits daily for one week, then weekly for four weeks utilizing the Physical Environment Monitoring Tool. The focus will be on maintaining dialysis equipment to provide safe and adequate care. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.</p> <p>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.</p> <p>The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution</p>	

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V 0544 Bldg. 00	<p>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.</p> <p>Based on observation, record review, and interview, the facility failed to ensure that patients prescribed BFR (blood flow rate) were maintained throughout the dialysis treatment in 3 of 7 records reviewed. (Patient 1, 2, and 6)</p> <p>Findings Include:</p> <p>1. A policy provided by the clinical manager on 8/5/2021 at 9:21 a.m., published on 9/29/2018 Version 3, titled, "Patient Assessment and Monitoring," indicated, but was not limited to, "Machine Parameters and Extracorporeal Circuit: Check machine settings and measurements. Check prescribed blood flow is being achieved or reason is documented in the medical record if unable to meet prescribed blood flow."</p> <p>2. A 7/16/2021 treatment sheet for patient 1 evidenced a prescribed BFR of 400 ml/min (milliliters per minute). Patient 1 ran on a BFR of 350 ml/min during entire treatment except for the</p>	V 0544	<p>of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: September 9, 2021</p> <p>On August 20, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy:</p> <ul style="list-style-type: none"> · Patient Assessment and Monitoring <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> · The registered nurse must evaluate each patient, review patient treatment prescription to 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) 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 	09/09/2021

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	<p>first 14 minutes of treatment. The facility failed to follow the prescribed blood flow rate.</p> <p>A 7/26/2021 treatment sheet for patient 1 evidenced a prescribed BFR of 400 ml/min. Patient 1 ran on a BFR of 300 ml/min during half of the treatment. The facility failed to follow the prescribed blood flow rate.</p> <p>3. A 7/23/2021 treatment sheet for patient 2 evidenced a prescribed BFR of 350 ml/min. Patient 2 ran on a BFR of 400 ml/min during the entire treatment. The facility failed to follow the prescribed blood flow rate.</p> <p>A 7/26/2021 treatment sheet for patient 2 evidenced a prescribed BFR of 350 ml/min. Patient 2 ran on a BFR of 400 ml/min during the entire treatment. The facility failed to follow the prescribed blood flow rate.</p> <p>A 7/28/2021 treatment sheet for patient 2 evidenced a prescribed BFR of 350 ml/min. Patient 2 ran on a BFR of 400 for the first half hour of treatment and then reduced to 375 ml/min for the remainder of the treatment. Documentation stating BFR 375 due to arterial pressure. The facility failed to follow the prescribed blood flow rate.</p> <p>A 7/30/2021 treatment sheet for patient 2 evidenced a prescribed BFR of 350 ml/min. Patient 2 ran on a BFR of 400 ml/min during the entire treatment. The facility failed to follow the prescribed blood flow rate.</p> <p>4. A 1/28/2019 treatment sheet for patient 6 evidenced a prescribed BFR of 425 ml/min. Patient 6 ran on a BFR of 400 ml/min during 2 hours of the prescribed treatment. The facility failed to follow the prescribed blood flow rate.</p>		<p>prior to treatment initiation: prescribed dialyzer, BFR, and prescribed dialysate composition per hemodialysis treatment physician's order.</p> <p>Effective August 23, 2021, the Clinical Manager or designee will conduct hemodialysis treatment sheet audits on a minimum of five 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 correct dialysate connection and documentation of BFR 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manger 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</p>	

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V 0715 Bldg. 00	<p>A 1/9/2019 treatment sheet for patient 6 evidenced a prescribed BFR of 425 ml/min. Patient 6 ran on a BFR of 400 ml/min during the entire treatment except the first 30 minutes of treatment. The facility failed to follow the prescribed blood flow rate.</p> <p>5. During an interview on 8/5/2021 at 9:15 a.m., the clinical manager was notified of wrong blood flow rates found on medical record review. No additional information was provided.</p> <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must-</p> <p>(2) Ensure that-</p> <p>(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;</p> <p>Based on observation, record review, and interview, the medical director failed to ensure staff followed policy and procedure by not checking stored medications on a monthly basis and not storing clean and sterile supplies appropriately.</p> <p>Findings Include:</p> <p>1. A policy published 3/4/2021, Version 6, provided by the clinic manager on 8/4/2021 at 1:05 p.m., titled "Medication Preparation and Administration," indicated, but was not limited to, "Monitoring Expired Medications: Expiration</p>	V 0715	<p>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. The in-service sheets are available in the clinic for review. Completion Date: September 9, 2021</p> <p>On August 20, 2021, the Facility Administrator held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:</p> <ul style="list-style-type: none"> · Medication Preparation and Administration · Storage of Supplies <p>Emphasis was placed on:</p> <ul style="list-style-type: none"> · Expiration dates for all stored medications are to be monitored on a monthly basis. · Expired medications are to be discarded via Fresenius Medical Services off-site program 	09/09/2021

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	<p>dates for all stored medications are to be monitored on a monthly basis. Expired medications are to be discarded via Fresenius Medical Services off-site program or in accordance with local and/or state law."</p> <p>2. A policy published 4/5/2021, Version 2, provided by the clinic manager on 8/4/2021 at 1:05 p.m., titled "Storage of Supplies," indicated, but was not limited to, "All clean or sterile supplies, except drums of concentrate, must be stored off the floor ..."</p> <p>3. During an observation on 8/4/2021 at 9:18 a.m., during the flash tour, two pre-filled syringes of Mircera (medication used to increase RBC production) 150 mcg were found in the medication refrigerator located in the medication preparation area. One expired on 6/2020 and the second expired on 2/2021.</p> <p>4. During an observation on 8/4/2021 at 9:47 a.m., during the flash tour, 1 case of face masks and 2 cases of sharps containers were observed to be placed directly on the floor in the supply room.</p> <p>5. During an interview on 8/4/2021 at 3:00 p.m. the administrator and clinical manager were made aware of the expired medications and supplies lying directly on the floor. The clinical manager stated she was aware of the expired medications and had already checked the remainder of the medications for expiration dates and stated the supplies found on the floor have been moved up off the floor.</p>		<p>or in accordance with local and/or state law.</p> <ul style="list-style-type: none"> All clean or sterile supplies, except drums of concentrate, must be stored off the floor. <p>Effective August 23, 2021, the Clinical Manager or designee will conduct medication and storage audits daily for one week, then weekly for four weeks utilizing the Physical Environment Monitoring Tool. The focus will be on removing expired supplies and ensuring all supplies are stored 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.</p> <p>The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinic 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,</p>	

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			<p>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.</p> <p>Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.</p> <p>Date of Completion: September 9, 2021</p>	