

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

PRINTED: 09/10/2021
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152640	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 08/23/2021
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE WELLS COUNTY	STREET ADDRESS, CITY, STATE, ZIP CODE 1100 S MAIN ST BLUFFTON, IN 46714
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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 19th, 20th, and 23rd of 2021.</p> <p>Facility Number: 011994</p> <p>At this Emergency Preparedness Survey, Fresenius Medical Care Wells County, was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid participating Providers and Suppliers, 42 CFR 494.62.</p> <p>QR Completed 8/30/2021 A4</p>	E 0000		
V 0000 Bldg. 00	<p>This visit was for a federal core ESRD (Core) recertification survey in conjunction with a COVID-19 infection control survey.</p> <p>Survey Dates: August 19th, 20th, and 23rd of 2021.</p> <p>Facility Number: 011994</p> <p>Census: 26 In-center Hemodialysis 6 Home Peritoneal Dialysis 0 Home Hemodialysis</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 0715 Bldg. 00	<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 procedures of monitoring for expired medications and supplies and for ensuring that medications were secured in a locked cabinet in 1 of 1 facilities.</p> <p>Findings Include:</p> <p>A 4/5/2021 version 6 policy titled, "Medication Preparation and Administration," provided by the clinic manager on 8/19/2021 at 2:32 p.m. indicated, but was not limited to, "Monitoring Expired Medications: 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 return program or in accordance with local and/or state laws" ... "Securement: All medications will be kept in a locked cabinet except when in use."</p> <p>A 7/4/2012 version 1 policy titled, "Expiration Dates of Sterile Supplies," provided by the clinic manager on 8/20/2021 at 1:45 p.m. indicated, but was not limited to, "Sterile items will be checked before use to ensure that they have not expired. Appropriately dispose of sterile items that have reached expiration date."</p>	V 0715	<p>On August 27, 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"> · Medication Preparation and Administration · Expiration Dates of Sterile Supplies <p>Education 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 or in accordance with local and/or state law. · All medications will be kept in a locked cabinet except when in use. <p>Effective August 30, 2021, the Clinic 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 discarding expired medications</p>	09/21/2021	

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	<p>During an observation on 8/19/2021 at 10:44 a.m. the following dialysis medications were found in an unlocked medication cabinet: 4 vials of Solu-Medrol 100 mg (used as an anti-inflammatory), 26 vials of Diphenhydramine (antihistamine used to treat allergies), 4 vials of Adrenalin (used to severe asthma attacks and allergic reactions), 11 bottles of Calcitriol tablets 0.25 mcg and 14 bottles of Calcitriol tablets 0.5 mcg (used to treat and prevent low levels of calcium and bone disease), 1 bottle of Acetaminophen (used to treat minor aches and pains and reduce fever), 1 box of single use packets of Triple Antibiotic Ointment (used to prevent infection), 26 vials of Venofer 50 mg and 21 vials of Venofer 100 mg (used to increase red blood cells), 1 bottle of 30 mg Cincacalcet, 1 bottle of 60 mg Cincacalcet, 1 bottle of 90 mg Cincacalcet (used to decrease calcium in the blood), 1 box of Nitrostat 0.4 mg tablets (used to treat and prevent chest pain), 2 vials of 50% Dextrose Injection 25 grams/50 milliliter (used to treat low blood glucose levels), and 3 boxes of Oseltamivir Phosphate capsules (10 tablets per box, used to treat influenza).</p> <p>During an observation on 8/19/2021 at 10:44 a.m., 4 vials of Diphenhydramine were found to be expired as of July 2021, located in a cabinet at the medication preparation area.</p> <p>During an observation on 8/19/2021 at 10:44 a.m. 1 bottle of RPC E-Z Blood Leak Test Strips (used to test for blood) were found to be expired on 9/30/2020, located in a cabinet at the medication preparation area.</p> <p>During an interview on 8/19/2021 at 11:16 a.m. the clinic manager was made aware of the findings of expired medications and blood leak test strips</p>		<p>and maintaining medications in locked cabinets 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, 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>		

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	found in the medication preparation area. These items were immediately removed from stock and no further information was provided. The clinic manager was also advised of the unsecured medications found in the cabinets at the medication preparation area and stated she was unaware of the need to have medications locked during business hours. Stated they are locked each night prior to leaving the facility.				