

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152654	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 04/11/2019
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE FISHERS	STREET ADDRESS, CITY, STATE, ZIP COD 13648 OLIVIA WAY FISHERS, IN 46037
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E 0000 Bldg. 00	<p>A Recertification Survey was conducted by Healthcare Management Solutions, LLC on behalf of the Centers for Medicare & Medicaid (CMS). The facility was found not to be in compliance with the requirements of CFR 42, Subsection 494.62- Condition for Coverage for Emergency Preparedness for End-Stage Renal Disease (ESRD) Facilities.</p> <p>Survey Dates: 04/09/19 - 04/11/19</p> <p>Total facility census: 102</p> <p>In-Center Hemodialysis (ICHD): 66</p> <p>Home Hemodialysis (HHD): 6</p> <p>Peritoneal Dialysis (PD): 30</p> <p>Nocturnal: 0</p> <p>Pediatrics: 0</p> <p>Sample Size: 10</p> <p>Network 5 was contacted after entrance</p>	E 0000		
E 0004 Bldg. 00	<p>Based on interview and review of the facility's Emergency Preparedness Plan (EPP), the facility failed to annually update the EPP. This failure had the potential to affect all of the dialysis patients receiving care in the facility and hindered the facility's ability to prepare for potential emergency</p>	E 0004	Plan of Correction Fresenius	06/05/2019

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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	<p>situations and keep patients safe during an emergency.</p> <p>Findings include:</p> <p>Review of the facility's EPP revealed there was no documentation that the EPP had been reviewed and updated annually.</p> <p>In an interview on 04/11/19, the Administrator/Director of Operations confirmed that there was no documentation of annual reviews and updates of the EPP.</p>		<p>Medical Care Fishers</p> <p>Global ID: 107404 Clinic: 8368 Recertification Survey Date of Survey: April 11, 2019 <u>E004 Develop EP Plan, Review and Update Annually CFR(s): 494.62(a)</u></p> <p>The Clinic Manager/designee will educate and elicit input from relevant staff by 5-20-19 on the expectations and responsibilities to comply with the following policies and procedures:</p> <ul style="list-style-type: none"> ·FMS-CS-IC-II-130-014A Guidelines for Emergency Preparedness Policy <p>Education emphasis was placed on:</p> <ul style="list-style-type: none"> ·The ESRD facility will develop, establish, and maintain a comprehensive emergency preparedness program. ·The ESRD facility will evaluate and update the Emergency Preparedness Plan at least annually. ·Documentation of the annual tabletop and full-scale exercises will be, but is not limited to, the exercise plan, the AAR, and any additional documentation used by the facility to support the exercise. ·All documentation will be placed in the Facility Specific Emergency Book. <p>·Note: ["Testing §482.15 for</p>	
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			<p>hospitals and §485.625(a) for CAH”] does not apply to ESRD facilities.] Fresenius Kidney Care Fishers Dialysis is an ESRD Facility.</p> <p>·Note: [“Network 5 was contacted after entrance” is documented in SOD.] Fresenius Kidney Care Fishers is in ESRD Network 9.</p> <p>On 5-21-19 Clinical Manager held a Governing Body meeting to review and update the Emergency Preparedness Plan. The Emergency Preparedness Plan will be audited and monitored quarterly in the Quality Assessment Improvement meeting. The Governing Body will continue on-going annual review of the Emergency Preparedness Plan.</p> <p>Any ongoing non-compliance by staff, per the Conditions for Coverage and the Fresenius Kidney Care policy, will be addressed through corrective action as appropriate.</p> <p>The Clinical Manager is responsible for reviewing, analyzing, and trending all data and audit results as related to this Plan of Correction prior to presenting to the QAI committee monthly.</p> <p>The Director of Operations is responsible for presenting the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies</p>	

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E 0013 Bldg. 00	<p>Based on observation, interview, and review of the facility's Emergency Preparedness Plan (EPP) the facility failed to implement the EEP procedure related to available emergency equipment. This failure had the potential to affect all the dialysis patients receiving care in the facility during an emergency and hindered the facility's ability to prepare for potential emergency situations and keep patients safe during an emergency.</p> <p>Findings include:</p> <p>Observations on 4/09/19 at 10:20 AM of the facility's emergency equipment locked cart revealed the following expired emergency</p>	E 0013	<p>at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI committee is responsible for providing oversight, review findings, and take actions as appropriate. 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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: June 5, 2019</p> <p><u>E013 Development of EP Policies and Procedures</u> <u>CFR(s): 494.62(b)</u> The Clinic Manager/designee will educate and elicit input from relevant staff by 5-20-19 on the expectations and responsibilities to comply with the following policies and procedures: ·FMS-CS-IC-II-130-014A Guidelines for Emergency Preparedness Policy ·FMS-CS-IC-II-130-007A Emergency Equipment and Supplies Policy Education emphasis was placed</p>	06/05/2019	

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	<p>medications: two doses of Solumedrol (for steroid used as anti-inflammatory) expired 12/2018, three 0.9% sodium chloride 1,000 ml bags (normal saline used in dialysis) expired 1/2019 and one 0.9% sodium chloride 1,000 ml bag expired 3/2019.</p> <p>In an interview on 4/10/19 at 10:00 AM, the Director of Operations/Administrator verified expired emergency supplies are to be removed and replaced prior to expiration. The Director of Operations/Administrator stated the emergency supplies expiration should be verified monthly.</p> <p>Review of the facility's policy titled, "Emergency Medications, Equipment and Supplies" revised 11/07/18 indicated, "The emergency cart must be; Locked when not in use; Checked monthly or after use for contents, expiration dates..."</p>		<p>on:</p> <ul style="list-style-type: none"> -The following minimum emergency supplies and equipment must be on the premises at all times, clean, functional, accessible and immediately available: <ul style="list-style-type: none"> -Automated External Defibrillator (AED) -Oxygen, tubing and masks/cannulas -Emergency medications -Suction machine, disposable catheter and canisters -Disposable Ambu Bag with face mask -IV solutions and administration sets -Cardiac back board -Oral Airway -CPR pocket mask -The emergency cart will be checked monthly or after use for contents, expiration dates, cleanliness and proper functioning of all equipment. -An itemized log will be kept indicating the contents and expiration dates of contents. Items approaching expiration will be reordered and replaced prior to the actual expiration date. -Note: ["PACE at §460.84(b):"] policies and procedures does not apply to ESRD facilities. Fresenius Kidney Care Fishers Dialysis is an ESRD Facility. Effective 5-21-19, the Clinical Manager or designee will conduct 	

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			<p>emergency cart supply audits one time weekly for one month, then every two weeks for one month utilizing the Medication Supply and Storage Monitoring Tool. The focus will be on verification of expiration dates on supplies and replacement prior to expiration dates. Once 100% compliance is sustained, monitoring will be completed monthly per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.</p> <p>Any ongoing non-compliance by staff, per the Conditions for Coverage and the Fresenius Kidney Care policy, will be addressed through corrective action as appropriate.</p> <p>The Clinical Manager is responsible for reviewing, analyzing, and trending all data and audit results as related to this Plan of Correction prior to presenting to the QAI committee monthly.</p> <p>The Director of Operations is responsible for presenting the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI committee is responsible for providing oversight, review findings, and take actions as appropriate.</p>	

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V 0000 Bldg. 00	<p>A Recertification (CORE) Survey was conducted by Healthcare Management Solutions, LLC on behalf of the Centers for Medicare & Medicaid Services (CMS). The facility was found not to be in compliance with the requirements of 42 CFR, Part 494, Subparts A, B, C, and D Conditions for Coverage for End-Stage Renal Disease Facilities.</p> <p>Survey Dates: 04/09/19 through 04/11/19</p> <p>Total facility census: 102</p> <p>In-Center Hemodialysis: 66</p> <p>Home Hemodialysis (HHD): 6</p> <p>Peritoneal Dialysis (PD): 30</p> <p>Nocturnal: 0</p> <p>Pediatrics: 0</p> <p>Sample Size: 10</p>	V 0000	<p>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.</p> <p>Documentation of education, monitoring, QAI, and Governing Body is available for review.</p> <p>The Clinic Manager is responsible for overall compliance.</p> <p>Completion Date: June 5, 2019</p>	

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V 0597 Bldg. 00	<p>Network 5 was contacted after entrance.</p> <p>494.100(c)(1)(vi) H-PROVIDE ORDERED SUPPLIES/EQUIPMENT Services include, but are not limited to, the following: (vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.</p> <p>Based on record review, staff interview and review of the facility's policy and procedure, licensed staff failed to follow the policy and procedure for monitor Home Treatment log documentation of the peritoneal dialysis treatments. Specifically, licensed staff failed to monitor the patient's daily weights for one of one patient (Patient (P) 10) Home Peritoneal Therapy. This failure had the potential to adversely affect the patients' cardiovascular and nutritional status and health.</p> <p>Findings include:</p> <p>Review of P0's medical record indicated he/she received Home Peritoneal Dialysis within a Long-Term Care (LTC) facility. Review of 44 daily "Continuous Cycling Peritoneal Dialysis (CCPD) (automated cyler that performs multiple exchanges at night while you sleep) records" dated 02/08/19 until 4/08/19 indicated 27 of 44 missing the patient's weight (the weight assists the dialysis facility staff adjust the dialysis treatment time, review for weight gain or loss). The documentation from the nephrologist exam dated 02/22/19 indicated the patient's weight as 118.14 lbs., the last documented weight on the</p>	V 0597	<p>V597 H-PROVIDE ORDERED SUPPLIES/EQUIPMENT CFR(s): 494.100(c)(1)(vi) The Clinical Manager will educate staff on 4/11/2019 on the expectations and responsibilities to comply with the following policies and procedures: ·FMS-CS-HT-I-200-010A Patient Home Record Keeping Policy ·FMS-CS-HT-I-200-008A Home Patient Responsibilities Policy ·FMS-CS-HT-I-200-005A Home Visits Policy ·FMS-CS-HT-I-200-008D1 PD Home Patient Responsibilities Consent Form Education emphasis was placed on: ·Ensuring the facility receives and reviews completed self-monitoring data and other information from self-care patient or their designated caregiver at least every 2 months; and maintain this information in the patient's medical record.</p>	06/05/2019

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	<p>CCPD record on 03/19/19 indicated the patient's weight as 104.2 lbs. with a weight loss of 13.94 lbs.</p> <p>In an interview on 4/11/19 at 11:40 AM, Staff Nurse 12 explained the weight should be documented daily, faxed by the LTC facility and reviewed by the facility's dialysis staff weekly. Staff Nurse 12 agreed the missing documentation should have been addressed and reviewed by the home treatment facility staff.</p> <p>Review of the facility's policy and procedure titled, "Patient Home Record Keeping" effective 3/07/12 stated, "The treatment log is used to monitor patient weight, blood pressure, solution selection..."</p>		<ul style="list-style-type: none"> -Ensure Home Therapy staff and patients understand the treatment log is used to monitor patient weight, blood pressure, solution selection, ultrafiltration, medications and compliance with treatment regimen. -Ensuring that all Home Therapy staff understands the importance of proper review and reinforcement of patient responsibilities of complete and correct data reporting. -Ensuring that all patients and/or caregivers understand the importance of complete and accurate documentation of home dialysis treatment data. -Home records will be reviewed by Home Program nursing staff during patient monthly clinic visits to identify trends or omissions. Any issues will be addressed by the RN upon receipt. <p>Beginning 4/18/2019 and on the next patient's attended visit, the home therapy RN's will re-educate each patient and/or patient authorized caregivers on the policies listed and receive acknowledgement utilizing the following:</p> <ul style="list-style-type: none"> -FMS-CS-HT-I-200-008D1PD Home Patients Responsibilities Consent <p>Effective 4/12/2019, the Clinic Manager or designee will conduct home therapy treatment sheet audits on 100% of all current records, then every two</p>	

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			<p>weeks for three months upon receipt of treatment sheets utilizing the Medical Records Audit Tool. The focus will be on complete and accurate home therapy treatment sheets. Once 90% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body.</p> <p>Any ongoing non-compliance by staff, per the Conditions for Coverage and the Fresenius Kidney Care policy, will be addressed through corrective action as appropriate.</p> <p>The Home Therapy Program Manager is responsible for reviewing, analyzing, and trending all data and audit results as related to this Plan of Correction prior to presenting to the QAI committee monthly.</p> <p>The Director of Operations is responsible for presenting the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues.</p> <p>The QAI committee is responsible for providing oversight, review findings, and take actions as appropriate.</p> <p>The Governing Body is responsible for providing oversight to ensure the Plan of Correction, as written</p>	

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

PRINTED: 05/20/2019

FORM APPROVED

OMB NO. 0938-039

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			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 responsible for overall compliance. Completion Date: June 5, 2019		