

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

PRINTED: 05/18/2021
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152641	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 04/21/2021
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NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE SCOTT COUNTY	STREET ADDRESS, CITY, STATE, ZIP CODE 130 N WESTAVIA BLVD SCOTTSBURG, IN 47170
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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 Date: April 19th, 20th, 21st of 2021</p> <p>Facility Number: 012200</p> <p>Census = 34 In-center Hemodialysis 0 Home Peritoneal Dialysis 0 Home Hemodialysis</p> <p>At this Emergency Preparedness survey, Fresenius Medical Care Scott County, was found in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62.</p> <p>Quality Review completed on 4/26/2021 A4</p>	E 0000		
V 0000 Bldg. 00	<p>This visit was for a federal ESRD (Core) recertification survey in conjunction with a COVID-19 infection control focused survey.</p> <p>Survey Dates: April 19th, 20th, and 21st of 2021.</p> <p>Facility Number: 012200</p> <p>Census: 34 In-Center Hemodialysis 0 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 0117 Bldg. 00	<p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>Based on observation, record review, and interview, the facility failed to ensure clean supplies were clearly separated from contaminated areas. This deficient practice had the potential to affect all patients.</p> <p>Findings include:</p> <p>A 4/5/2021, Version 2, policy titled, "Storage of Supplies" was provided by the administrator on 4/19/2021 at 2:29 p.m. The policy indicated, but was not limited to, "All supplies must be stored in</p>	V 0117	<p>On May 10, 2021, the Clinical Manager conducted a staff meeting to review the CMS survey findings, to provide staff reeducation and to reinforce the expectations and responsibilities of the facility staff on the following FKC policies:</p> <p>Access Assessment and Cannulation, with specific emphasis on: Tape from multi-use roll:</p>	06/10/2021	

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	<p>a clean, well lit, and climate-controlled environment."</p> <p>During an observation on 4/21/2021 at 11:25 p.m. evidenced pre-torn medical tape to be used for dialysis treatments, adhered to four different clipboards, stored on a bookshelf next to the nurse's station.</p> <p>During an interview with the administrator on 4/21/2021 at 11:45 p.m. administrator was notified of pre-torn tape adhered to clipboards on bookshelf next to nurse's station. Stated, she was going to go investigate this.</p>		<p>Tape must be prepared outside of the patient station to prevent risk of cross contamination. Tear strips of tape, tabbed at one end, and stack the number of pieces you need for cannulation. When you are ready to cannulate, go to the clean area and retrieve the stack of tape. The last piece of tape serves as your barrier and should not be used on the patient.</p> <p>Storage of Supplies: Effective immediately, tape will be maintained in a drawer at the designated clean medication prep area.</p> <p>Emphasis was placed on: Tape must be torn outside of the patient station and maintained in a designated clean area to prevent risk of cross contamination.</p> <p>Effective May 11, 2021 Clinical Manager or designee will conduct daily observational infection control audits of staff preparing tape from a multi-use roll with appropriate storage in a designated clean area x two (2) weeks. Once compliance 100% is achieved, the Governing Body will decrease frequency to weekly x 2 weeks. Once 100% compliance is sustained the Governing body will then resume regularly scheduled audits as based upon the QAI calendar.</p>	

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V 0190	494.40(a) SOFTENERS-AUTO		<p>The Medical Director will review the results of the observational infection control audits each month at the QAI Committee meeting.</p> <p>The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: 6/10/2021</p>	

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Bldg. 00	<p>REGENERATE/TIMERS/SALT LVL</p> <p>5.2.4 Softeners: auto regen/timers/salt/salt level Prior to exhaustion, softeners should be restored; that is, new exchangeable sodium ions are placed on the resin by a process known as "regeneration," which involves exposure of the resin bed to a saturated sodium chloride solution.</p> <p>5.2.4 Softeners Refer to RD62:2001, 4.3.10 Automatically regenerated water softeners: Automatically regenerated water softeners shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.</p> <p>The face of the timers used to control the regeneration cycle should be visible to the user.</p> <p>6.2.4 Softeners Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated.</p> <p>The softener brine tank should be monitored daily to ensure that a saturated salt solution exists in the brine tank. Salt pellets should fill at least half the tank. Salt designated as rock salt should not be used for softener regeneration since it is not refined and typically contains sediments and other impurities that may damage O-rings and pistons and clog orifices in the softener control head.</p>			

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	<p>Based on observation, record review, and interview the facility failed to accurately monitor and maintain the water softener equipment and allowed the brine tank salt level to fall below the 50% manufacturer's requirement level. This deficient practice had the potential to affect all patients.</p> <p>Findings include:</p> <p>An 11/2/2020, Version 2 policy titled, "Water Softener" was provided by the facility administrator on 4/19/2021 at 2:29 p.m. The policy indicated, but was not limited to, "Salt levels inside brine tanks will be maintained at a minimum of half full."</p> <p>Observation during the facility flash tour on 4/19/2021 at 12:18 p.m., evidenced the salt pellet level of the brine cylinder at 25% full.</p> <p>During an interview with the water treatment technician on 4/20/2021 at 10:50 a.m. when asked about the brine level he stated the brine tank "is to be ½ full, I know there was a problem with that yesterday."</p>	V 0190	<p>On 4/19/2021, the Bio-Medical Technician placed salt pellets into the brine cylinder to ensure that the salt level in the cylinder was half full per FKC Policy.</p> <p>On May 10, 2021 the Clinical Manager conducted a staff meeting to review the CMS Survey findings, to re-educate and reinforce the expectations and responsibilities of the facility staff on the following FKC policies and procedures: Water Softener Emphasis was placed on: Ensure that the level of salt in the brine cylinder is maintained at half full.</p> <p>Effective May 11, 2021, the Clinical Manager or designee will conduct daily observational audits of the salt pellet level in the brine tank x two (2) weeks. Once compliance 100% is achieved, the Governing Body will decrease frequency to weekly observational audits of the salt pellet level in the brine tank x two (2) weeks. Once 100% compliance is sustained the Governing Body will then resume regularly scheduled audits based on QAI calendar.</p> <p>The Medical Director will review the results of the brine tank salt pellet level observational audits each month at the QAI Committee meeting.</p> <p>The Clinical Manager is responsible to review, analyze and</p>	06/10/2021	

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V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and		trend all data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance. Completion Date: 6/10/2021	

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	<p>nonphysician providers;</p> <p>Based on observation, record review, and interview, the medical director failed to ensure that staff followed policy and procedure to prevent clean supplies from being placed directly on the facility storage floor. This deficient practice had the potential to affect all patients.</p> <p>Findings include:</p> <p>A 4/5/2021, Version 2, policy titled, "Storage of Supplies" was provided by the administrator on 4/19/2021 at 2:29 p.m. The policy indicated, but was not limited to, "All clean or sterile supplies, except drums of concentrate, must be stored off the floor and a minimum of eighteen inches in a sprinklered facility from the ceiling."</p> <p>Observation during the facility flash tour on 4/19/2021 at 12:18 p.m., evidenced 9 bags of salt pellets and 7 boxes of vinegar placed directly on floor.</p> <p>During an interview with the administrator on 4/19/2021 at 2:29 p.m. when given the policy "Storage of Supplies" she stated "obviously, supplies should not be sitting directly on the floor."</p>	V 0715	<p>On 4/19/2021, the Bio-Medical Technician moved the 9 bags of salt pellets and 7 boxes of vinegar from the facility storage floor, and placed them on pallets to ensure clean supplies were not stored directly on the facility storage floor.</p> <p>On April 28, 2021 the Director of Operations met with the Medical Director to review and provide re-education on the following:</p> <p>CMS Statement of Deficiencies/ Survey findings Storage of Supplies Policy.</p> <p>V715: The Medical Director must ensure that all policies and procedures relative to patient admission, patient care, infection control and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non physician providers.</p> <p>On May 10, 2021, the Clinical Manager conducted a staff meeting to review the survey findings, to provide staff re-education and to reinforce the expectations and responsibilities of the facility staff on the following FKC policies and procedures: Storage of Supplies Emphasis was placed on: The Medical Director is responsible to provide supervision</p>	06/10/2021	

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			<p>and ensure that all policies and/or procedures are followed. Ensure that clean and/or sterile supplies are stored off of the facility storage floor. Effective May 11, 2021 the Clinical Manager or designee will conduct daily observational audits of the facility storage room to ensure that no supplies are stored directly on floor x two (2) weeks. Once 100% compliance is achieved, the Governing Body will decrease frequency to weekly observational audits of the facility storage room weekly x two (2) weeks. Once 100% compliance is sustained the Governing body will then resume regularly scheduled audits as based upon the QAI calendar. The Governing Body is responsible to provide direct oversight to the Medical Director responsibilities and actions to ensure that all policies and procedures relative to patient admission, patient care, infection control and safety are adhered to by all individuals who treat patients in the facility. The Medical Director will review the results of observational storage room audits each month at the QAI Committee meeting.</p> <p>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</p>	

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			<p>Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review.</p> <p>The Clinic Manager is responsible for overall compliance. Completion Date: 6/10/2021</p>	