

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

PRINTED: 06/11/2018
FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 152582		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING		X3) DATE SURVEY COMPLETED 05/24/2018	
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE SPENCER				STREET ADDRESS, CITY, STATE, ZIP COD 11 CRANE AVE SPENCER, IN 47460			
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E 0000 Bldg. 00	An Emergency Preparedness Survey was conducted by the Indiana State Department of Health in accordance with 42 CFR 494.62. Survey Date: May 22, 23, and 24 of 2018 Facility Number: 010328 Provider Number: 152582 Census = 30 At this Emergency Preparedness survey, Fresenius Medical Care Spencer was found in compliance with Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers, 42 CFR choose appropriate program CFR 494.62.			E 0000			
V 0000 Bldg. 00	This survey was for a federal ESRD (Core) recertification survey. Survey Date: May 22, 23, and 24 of 2018 Facility Number: 010328 Provider Number: 152582 Census: 30 in-center hemodialysis 0 home peritoneal dialysis 0 home hemodialysis			V 0000			
V 0143 Bldg. 00	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate						

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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	compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and Based on observation, interview, and policy review the facility failed to ensure expired Epogen [medication used to treat low red blood cells] and Tubersol [test used to aid in the diagnosis of tuberculosis infection] multi-dose vials were not available for use. Findings include: 1. A facility policy titled, "Medication Preparation and Administration" with an issue date and effective date of January 28, 2015 states, "When preparing medications if the vial is not used immediately in its entirety, the nurse must place the date and time the vial was opened on the medication label along with the nurse initials ... Any open multi dose vials must be discarded 28 days after opening (Epogen is 21 days ...)" 2. A CDC [Centers for Disease Control and Prevention] website www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html states, " ... 5. ... If a multi-dose has been opened or accessed (e.g., needle-punctured), the vial should be dated and discarded within 28 days ..." 3. The US Food and Drug Administration approved product information website (www.fda.gov/BiologicsBloodVaccines/ApprovedProducts/ucm114904.htm; paged last update 3/26/18) contained a document/package insert titled Tuberculin Purified Protein Derivative (Mantoux) TUBERSOL which states, " ... A vial of TUBERSOL which has been entered and in use for			V 0143	On 5/22/18, the Director of Operation held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·FMS-IS-IC-120-040A Medication Preparation and Administration Policy ·FMS-IS-IC-120-040C Medication Preparation and Administration Procedure Emphasis was placed on: ·Monitoring all open multidose medications for expiration dates ·Date/time/initial open multidose vials Effective 5/31/18 Clinical Manager or designee will conduct weekly audits utilizing RN monthly medication review for 30 days and monthly thereafter. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the RN monthly medication review per QAI calendar. Any ongoing non-compliance by staff, per the Conditions for Coverage and the FMC policy, will be addressed with corrective action as appropriate. The Clinical Manger is responsible to review, analyze and trend all		06/30/2018

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V 0729 Bldg. 00	30 days should be discarded ... Do not use after expiration date ..." 4. A package insert on Epogen [https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/103234s5158ppi.pdf], 09/2017, states "... Throw away multi dose vials of Epogen no later than 21 days from the first day that you put a needle into the vial ..." 5. During a flash tour on 5/22/18 at 1:50 p.m., the contents of the refrigerator located in the facility were observed. An open Tubersol vial [lot# C5470BA] labeled with tape stated the vial was opened on 4/14/18. An opened Epogen vial [lot # 1078833] did not contain labeling that stated the date, time, and nurse initials of when the vial was opened. The facility failed to properly label opened multi dose vials as well as following CDC and US Food and Drug Administration guidelines for discarding expired multiple-dose vial medications. 6. During an interview on 5/22/18 at 1:52 p.m., the clinical manager acknowledged the lack of proper labeling on an opened Epogen vial and that the expired medications should have been discarded. 494.170(b)(1) MR-COMplete RECORDS PROMPTLY (1) Current medical records and those of discharged patients must be completed promptly. Based on record review and interview, the facility failed to ensure staff monitored patient's vital signs every 30 minutes during hemodialysis treatments in 4 of 4 records reviewed. (Patients #2, 4, 8, and 10)			V 0729	data and Monitor/Audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. 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. The in-service sheets are available in the clinic for review. The deficiency will be corrected by June 30. On 5/22/18, the Director of Operation held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·FMS-CS-IC-I-110-133A Patient Monitoring During Patient		06/30/2018

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	Findings include: 1. A facility policy titled, "Patient Monitoring During Patient Treatment" with an issue date of July 4, 2012 and an effective date of August 20, 2014 states, " ... Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently, as needed ..." 2. Reviewed clinical record #2 on 5/22/18 with the following findings. A. On 5/19/18 at 1:02 p.m. blood pressure of 103/59 was recorded. At 1:43 p.m. the next recorded blood pressure was 98/65. The time between assessments was 41 minutes. 3. Reviewed clinical record #4 on 5/23/18 with the following findings. A. On 5/5/18 at 2:35 p.m. blood pressure of 123/65 was recorded. At 2:35 p.m. the next recorded blood pressure was 119/62. The time between assessments was 1 hour. 4. Reviewed clinical record #8 on 5/23/18 with the following findings. A. On 5/16/18 at 1:01 p.m. blood pressure of 140/55 was recorded. At 1:40 p.m. the next recorded blood pressure was 135/60. The time between assessments was 39 minutes. B. On 5/16/18 at 2:11 p.m. blood pressure of 142/60 was recorded. At 3:03 p.m. the next recorded blood pressure was 121/55. The time between assessments was 52 minutes. C. On 5/14/18 at 12:00 p.m. blood pressure of 161/61 was recorded. At 12:43 p.m. the next				Treatment ·FMS-CS-IC-I-110-134A Determination of Blood Pressure Policy ·FMS-CS-IC-I-110-134C Determination of Blood Pressure Procedure Emphasis was placed on: ·Monitoring and documenting patient's blood pressures every 30 minutes Effective 5/28/18 Clinical Manager or designee will conduct daily audits of each patient treatment records for one month, weekly for one month, monthly thereafter utilizing Patient Treatment Documentation QAI Audit. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Patient Treatment Documentation QAI Audit per QAI calendar. Any ongoing non-compliance by staff, per the Conditions for Coverage and the FMC policy, will be addressed with corrective action as appropriate. 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 QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate.		

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	recorded blood pressure was 142/61. The time between assessments was 43 minutes. D. On 5/9/18 at 1:02 p.m. blood pressure of 132/68 was recorded. At 2:04 p.m. the next recorded blood pressure was 116/53. The time between assessments was 62 minutes. 5. Reviewed clinical record #10 on 5/22/18 with the following findings. A. On 5/14/18 at 3:04 p.m. blood pressure of 112/57 was recorded. At 3:46 p.m. the next recorded blood pressure was 113/59. The time between assessments was 42 minutes. B. On 5/9/18 at 12:02 p.m. blood pressure of 164/102 was recorded. At 12:43 p.m. the next recorded blood pressure was 170/100. The time between assessments was 41 minutes. C. On 5/9/18 at 2:07 p.m. blood pressure of 131/60 was recorded. At 3:11 p.m. the next recorded blood pressure was 121/61. The time between assessments was 64 minutes. D. On 5/2/18 at 11:51 a.m. blood pressure of 139/85 was recorded. At 1:04 p.m. the next recorded blood pressure was 126/81. The time between assessments was 73 minutes. E. On 4/30/18 at 1:04 p.m. blood pressure of 125/83 was recorded. At 2:00 p.m. the next recorded blood pressure was 125/86. The time between assessments was 56 minutes. F. On 4/30/18 at 2:36 p.m. blood pressure of 140/81 was recorded. At 3:35 p.m. the next recorded blood pressure was 121/71. The time between assessments was 59 minutes.				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. The in-service sheets are available in the clinic for review. The deficiency will be corrected by June 30.		

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	6. In an interview on 5/23/18 at 1:50 p.m. the administrator was made aware that blood pressures were not monitored every 30 minutes and no additional information was provided.						