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

FORM APPROVED
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152501	A. BUILDING 00 B. WING	08/21/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE GARY	3290 GRANT ST GARY, IN 46408

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V 0000 Bldg. 00	This visit was for a Federal complaint of an ESRD provider. Survey Dates: 08/20/2024 to 08/21/2024 Complaint # 440098 was investigated; standard level deficiencies, related and unrelated, were cited. Census by Modality: In-Center Hemodialysis: 87 Home Hemodialysis: 0 Home Peritoneal Dialysis: 17 Total Active Patient Census: 104 Approved in-center dialysis stations:24 Isolation room/waiver: 1 QR: 8/30/2024	V 0000		
V 0146 Bldg. 00	494.30(c)(2) IC-CATHETERS:GENERAL Based on observation and interview, the dialysis failed to ensure the staff provided central venous catheter (CVC) (catheter placed into a large vein) care per provider policy in 3 of 6 observations of CVC dialysis initiation care and 2 of 3 dialysis discontinuation of CVC care on 08/20/2024 and 08/21/2024. (Patient #1, 12, 20, 21, and 23). Findings include: 1. The Policy dated 05/06/2024 and titled, "Initiation of Treatment Using a Central Venous Catheter ... " indicated prior to initiation of a CVC	V 0146	V146 On 9/9/2024 and 9/10/2024, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: Initiation of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer Procedure Changing the Catheter Dressing Procedure	09/19/2024

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Wennikkia Booker	Director of Operations	09/09/2024

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determin other safegaurds 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 disclo 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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	a mask should be on the Patient, the hub of the CVC must be scrubbed with 70% alcohol pad for 10-15 seconds and any time caps are removed, or blood lines are disconnected to reduce the risk of contamination. 2. A Policy dated 02/05/2024 and titled, "Changing the Catheter Dressing Procedure," indicated apply chloraprep on the skin in a back-and-forth motion to allow the solution to penetrate the cell layers of the epidermis (top layer of skin) and to ensure the entire area of the catheter insertion site was cleansed with chloraprep (antiseptic) prior to the dressing (covering) was applied. 3. During observations on 8/20/24: A. Beginning at 9:50 AM at Station #17, Registered Nurse (RN) 1 was observed initiating dialysis of Patient #20 by wiping the CVC, the red and blue hubs (access line) for less than 2 seconds each with an alcohol swab, then RN 1 inserted syringes into each the hub. After pulling blood back into the syringes, RN 1 cleansed the red hub for less than 2 seconds with an alcohol swab and inserted a vacutainer (tube to draw labs), then RN 1 removed the vacutainer and syringe and cleansed the red and blue hub for less than 2 seconds with an alcohol swab and then Patient's dialysis was initiated. B. Beginning at 10:20 AM, at Station #15 Patient Care Technician (PCT) 4 was observed discontinuing dialysis of Patient #21's CVC by wiping the each hub, the blue and the red hub for less than 5 seconds each, using an alcohol swab and then PCT 4 capped the hubs. C. Beginning at 10:50 AM, during an observation		Emphasis was placed on: The patient must wear a mask for all procedures that require accessing the catheter. Disinfection of the Catheter Connections Threads and end of the luer lock (hub) must be scrubbed with 70% sterile alcohol pad ***for 10-15 seconds*** and any time caps are removed, or bloodlines are disconnected to reduce risk of contamination. Follow the steps below to clean the catheter exit site: Perform hand hygiene and don clean gloves. Remove swabstick from package by stick end without touching foam applicator. Handle only the stick portion. **2% Chlorhexidine and 70% alcohol:** Using gentle back and forth friction, clean the exit site beginning in the center and continuing outward the area of the size of the dressing to be applied (2 inches) in a concentric circle for 30 seconds and allow to dry a minimum of 30 seconds. If exudate or crusting is noted, an additional swabstick may be necessary to clean the exit site. • Applying CHG on the skin in a gentle back and forth motion allows the solution to penetrate the cell layers of the epidermis where 80% of microorganisms	

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	at station #16, Patient #23 was not wearing a mask , PCT 4 was observed discontinuing the CVC; PCT 4 wiped the red hub for 5 seconds with an alcohol swab and the blue hub was wiped for 6 seconds with an alcohol swab and then syringes were inserted into each hub, the red and blue, at 10:57 AM. Then PCT 4 gave Patient a mask to place over their mouth and nose. D. Beginning at 11:40 AM, during an observation of Patient #1 at Station #15, PCT 4 was observed wiping Patients' CVC exit site with a chloraprep (antiseptic) swab; PCT 4 wiped from the left side to the top and to the right side in a back and forth motion, and then turned over the swabbed and touched the CVC's insertion site, however PCT 4 did not clean around the insertion site. PCT 4 applied a dressing (insertion site cover) then wiped each of the 2 hubs with an alcohol sawp, wiped the red hub for 8 seconds and wiped the blue hub for 6 seconds, then syringes were inserted into the red and blue hub. 4. During an interview on 08/20/2024, beginning at 10:25 AM, RN 1 indicated the hubs of a CVC should be scrubbed with an alcohol swab for 1-2 minutes. 5. During an interview on 08/20/2024, beginning at 11:45 AM, RN 3 indicated the CVC hubs should be scrubbed with an alcohol swab for 30 seconds. 6. During an observations on 8/21/24, beginning at 10:25 AM, at Station #19 PCT 1 was observed providing care to Patient #12, observed to wipe Patients' CVC with a chloraprep swab, using a circular motion from the insertion site outward and then returned to the insertion site to swab again and then a dressing was applied. 7. During an interview on 08/21/2024, beginning at 11:00 AM, PCT 3 indicated a CVC site should be		reside. • Reminder: Chlorhexidine swab contains alcohol. The alcohol must vaporize to dry. Allow the area to dry for approximately 30 seconds. Do not blot or wipe away. If a dressing is applied prior to drying, the alcohol vapors will be trapped resulting in blistering of the skin. **If using povidone pad:** Using gentle friction, disinfect the exit site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds and allow to dry for at least 2 minutes. **If using 70% alcohol pad:** Using gentle friction, disinfect the access site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds and allow to dry. **If using ExSept Plus**: Using gentle friction, use one saturated 4x4 to disinfect the access site beginning in the center and continuing outward 2 inches in a concentric circle for 30 seconds. Discard and repeat with second 4x4. Allow to dry at least 2 minutes. Effective 9/11/2024, Clinical Manager will conduct weekly audits with focus on ensuring all patients are wearing mask anytime accessing the catheter; staff disinfect the threads and end of the leur lock of the central	

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	cleansed with chloraprep from the insertion side to the outside and do not touch the insertion site again with the chloraprep swab after inside to outside cleansing was completed, and indicated the hubs of the CVC should be cleansed with an alcohol swab for 15 seconds.		venous catheter for 10-15 seconds any time caps are removed, or bloodlines are disconnected; using gentle back and forth friction, clean the exit site beginning in the center and continuing outward the area of the size of the dressing to be applied (2 inches) in a concentric circle for 30 seconds and allow to dry a minimum of 30 seconds, utilizing Infection Control Audit Tool for 2 weeks, 3 times per week, alternating shifts, then weekly, 2 times per week for 2 additional 2 weeks or until 90% compliance is achieved utilizing Infection Control Audit Tool. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. 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	

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			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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. 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. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 09/19/24.	
V 0503 Bldg. 00	494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX Based on record review and interview, the dialysis facility failed to evidence a Patient's current individualized dialysis prescription was evaluated to meet the needs of a Patient, failed to evidence the Patient was assessed or the physician was notified in 1 of 1 Patients records reviewed with a	V 0503	V503 On 9/9/2024 and 9/10/2024, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure:	09/19/2024

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	documented fall (Patient #2). Findings include: 1. A policy dated 02/06/2023, titled, "Patient Safety Event Reporting and Documentation," indicated documentation of patient events should include patient assessment and documentation should include the physician was notified. 2. A Clinical Note Report dated 07/11/2024 indicated Patient #2 fell outside of the dialysis building when trying to get into the transportation van, Patient denied hitting his/her head and denied need to go to the Emergency Room and wanted to go home because his/her hand hurt. The Clinical Note failed to document if an assessment was attempted on Patient to include vital signs. 3. A Treatment Sheet dated 07/11/2024 for Patient #2 indicated Patient received a bolus of 7000 units of Heparin (blood thinner) during hemodialysis (process to clean the blood of a patient whose kidneys do not work normally). 4. During an interview on 08/20/2024, beginning at 6:15 PM, Patient #2 indicated he/she fell outside after dialysis and thought he/she had passed out because only remembered people were surrounding him/her and he/she did not understand what was going on. Patient #2 indicated he/she could not remember if he/she asked to go to the hospital and the driver of the transportation van and the Patient's family member had to assist Patient to get into his/her home. 5. During an interview on beginning at 10:15 AM, registered nurse (RN) 2 indicated Patient #2 fell		Patient Safety Event Reporting and Documentation Emphasis was placed on: Safety event results in mild to moderate patient clinical harm, not due to an underlying disease or condition. Requires additional monitoring, intervention, and/or medical care. When a Near Miss, Safety Event or Serious Safety Event occurs, staff are required to report, document, and review the event as noted in this policy. Staff are responsible for the timely completion of these policy requirements. Clinical Staff are required to report all Safety Events and Serious Safety Events to the patient's physician. Effective 09/11/2024, the Clinical Manager will conduct 10 treatment sheets daily, 3 times per week, alternating shifts, with a focus on all patient safety events, assessment patient after event, document and report to patient's physician per policy, with a review in QAI. The treatment sheet audit tool will be utilized for 2 weeks, 3 times per week; and then weekly 2 times per week for an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on	

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	when trying to get into transportation van while carrying bags, RN 2 indicated Patient refused an ambulance and the staff did not check Patient's vital signs, Patient denied hitting their head, and physician should have been notified and would have documented if the physician was notified. RN 2 indicated the Patient was not brought into the building for an evaluation. RN 2 indicated Patient did not have any visible injuries. 6. During an interview on 08/21/2024, beginning at 1:50 PM, the Administrator indicated after a Patient fall, the physician should be notified and there was not documentation that a physician was notified. The Administrator indicated Patient should have vitals signs assessed after the fall and if Patient refused assessment the physician should have been notified.		compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar 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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. 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	

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			effective and is providing resolution of the issues. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 09/19/24.	
V 0634 Bldg. 00	494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS Based on record review and interview, the dialysis facility failed to identify a Patient fall in the QAPI (quality assessment and performance improvement) program to limit the number of patients who are adversely affected by such occurrences in 1 of 1 Patient's records reviewed with a documented fall. (Patient #2). Findings include: 1. A policy dated 02/06/2023, titled, "Patient Safety Event Reporting and Documentation," indicated the policy was to provide guidelines for all clinical staff on identifying, reporting and documentation patient related safety events to provide a standardized process for the management of patient safety events. The policy indicated when a safety event occurred, staff are required to report, document and review the event. The policy indicated events that occurred outside the facility may be considered a serious safety event when related to the dialysis treatment or the care provided. The policy indicated the patient safety event should be reviewed during the QAPI program to perform an analysis of the events to identify trends to include preventability	V 0634	V634 On 9/9/2024 and 9/10/2024, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy and procedure: Patient Safety Event Reporting and Documentation Emphasis was placed on: The purpose of this policy is to provide guidelines for all clinical staff on identifying, reporting and documenting patient related Near Misses, Safety Events and Serious Safety Events in the In-Center and Home Therapy setting to: Provide a standardized process for management of all patient related safety events as defined in this policy Promote a culture of patient safety When a Near Miss, Safety	09/19/2024

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	and determine an opportunity for improvement. The policy indicated an unplanned descent to the floor or ground would indicate a fall and would be included in a patient safety event. 2. A Grievance Report dated 07/18/2024 indicated Patient #2 fell getting into a transportation van after dialysis treatment on 07/11/2024. 3. During an interview on 08/21/2024, beginning at 10:15 AM, Registered Nurse 2 indicated Patient #2 fell attempting to get into the transportation van and indicated they did not complete an incident report. 4. During an interview on 08/21/2024, beginning at 1:50 PM, the Administrator indicated an adverse event report was not completed for Patient #2 after the reported fall, and should have been completed.		Event or Serious Safety Event occurs, staff are required to report, document, and review the event as noted in this policy. Staff are responsible for timely completion of these policy requirements. Events occurring outside the facility may be considered a Serious Safety Event when related to the dialysis treatment and/or care provided. Contact Clinical Services to determine if the event meets Safety Event criteria. Patient Safety Events should be reviewed during Quality Assessment and Performance Improvement (QAPI) Program utilizing the eQUIP Dashboard in accordance with the Quality Assessment and Performance Improvement Program Policy. Facilities should perform an analysis of all events and complete all documentation in accordance with the QAPI process and tools, as required by Policy and the Conditions for Coverage. Effective 09/11/2024, the Clinical Manager will conduct 10 treatment sheets daily, 3 times per week, alternating shifts, with a focus on all patient safety events, are documented and reported to patient’s physician per policy with a review in QAI. The treatment sheet audit tool will be utilized for 2 weeks, 3 times per week; and then weekly 2 times per week for	

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			an additional 2 weeks or until 100% compliance is achieved. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar 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 for providing oversight, reviewing findings, and taking actions as appropriate. The root cause analysis process is utilized to develop the Plan of Correction. The Plan of correction is reviewed in QAI monthly. The Governing Body is responsible	

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			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. The QAI and Governing Body minutes, education and monitoring documentation are available for review at the clinic. Completion 09/19/24.	