



IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
RICHARD M. ARMSTRONG – Director

TAMARA PRISOCK—ADMINISTRATOR
DIVISION OF LICENSING & CERTIFICATION
DEBBY RANSOM, R.N., R.H.I.T. – Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
P.O. Box 83720
Boise, Idaho 83720-0009
PHONE: (208) 334-6626
FAX: (208) 364-1888
E-mail: fsb@dhw.idaho.gov

CERTIFIED MAIL: 7000 0520 0023 1950 8572

February 8, 2016

Wendy Casper, Administrator
Idaho Kidney Center
98 Poplar Street
Blackfoot, ID 83221

RE: Idaho Kidney Center, Provider #132515

Dear Ms. Casper:

Based on the survey completed at Idaho Kidney Center, on February 1, 2016, by our staff, we have determined Idaho Kidney Center is out of compliance with the Medicare ESRD Condition for Coverage of, **CFC-QAPI (42 CFR 494.110)**. To participate as a provider of services in the Medicare Program, an ESRD must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

The deficiencies, which caused this condition to be unmet, substantially limit the capacity of Idaho Kidney Center, to furnish services of an adequate level or quality. The deficiencies are described on the enclosed Statement of Deficiencies/Plan of Correction (CMS-2567).

You have an opportunity to make corrections of those deficiencies, which led to the finding of non-compliance with the Condition for Coverage referenced above by submitting a written Credible Allegation of Compliance/Plan of Correction.

An acceptable Plan of Correction contains the following elements:

- Action that will be taken to correct each specific deficiency cited;

Wendy Casper, Administrator
February 8, 2016
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- Description of how the actions will improve the processes that led to the deficiency cited;
- The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;
- A completion date for correction of each deficiency cited must be included;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the ESRD into compliance, and that the ESRD remains in compliance with the regulatory requirements;
- The plan must include the title of the person responsible for implementing the acceptable plan of correction; and
- The administrator's signature and the date signed on page 1 of each form.

Such corrections must be achieved and compliance verified by this office, before March 17, 2016. To allow time for a revisit to verify corrections prior to that date, it is important that the completion dates on your Credible Allegation/Plan of Correction show compliance no later than March 7, 2016.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **February 18, 2016.**

Failure to correct the deficiencies and achieve compliance will result in our recommending that CMS terminate your approval to participate in the Medicare Program. If you fail to notify us, we will assume you have not corrected.

We urge you to begin correction immediately.

If you have any questions regarding this letter or the enclosed reports, please contact me at (208) 334-6626, option 4.

Sincerely,



TRISH O'HARA
Health Facility Surveyor
Non-Long Term Care



NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

TO/pmt

Enclosures

cc: Debra Ransom, R.N., R.H.I.T., Bureau Chief
Linda Harris, CMS Region X Office

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

PRINTED: 02/05/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 132515	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 02/01/2016
NAME OF PROVIDER OR SUPPLIER IDAHO KIDNEY CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 98 POPLAR STREET BLACKFOOT, ID 83221		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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	
V 000	INITIAL COMMENTS [CORE] The following deficiencies were cited during the recertification survey of your ESRD facility from 1/25/16 - 2/1/16. The surveyor conducting the survey was: Trish O'Hara, RN, HFS Acronyms used in this report include: ATOM - Area Technical Operations Manager CVC - Central Venous Catheter DO - Director of Operations ICHD - Incenter Hemodialysis MCG - micrograms PM - Preventive Maintenance QAPI - Quality Assurance Performance Improvement	V 000			
V 112	494.30(a) IC-CDC MMWR 2001 The facility must demonstrate that it follows standard infection control precautions by implementing- (1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National	V 112			

RECEIVED
FEB 18 2016
FACILITY STANDARDS

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X8) DATE _____

[Signature] DIRECTOR OF OPERATIONS

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days 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 disclosable 14 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.


DEPARTMENT OF HEALTH AND HUMAN SERVICES
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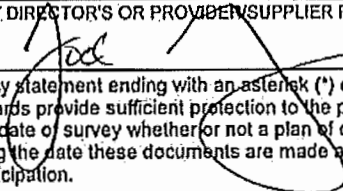
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V 112	494.30(a) IC-CDC MMWR 2001 The facility must demonstrate that it follows standard infection control precautions by implementing- (1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National	V 112		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE JOEL H. GROOMS DIRECTOR OF OPERATIONS	(X8) DATE 2/18/16
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V 112	<p>Continued From page 1</p> <p>Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.</p> <p>The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009.</p> <p>This STANDARD is not met as evidenced by: Based on observation, policy and procedure review and staff interview, it was determined the facility failed to ensure staff maintained aseptic technique when performing a CVC dressing change for 1 of 3 patients (Patient #4) who dialyzed using a CVC and whose care was observed. This created the potential for contamination to the open exit site from the skin surface. The findings include:</p> <p>A facility policy titled Changing the Catheter Dressing, revised 1/6/14, instructed staff to "clean the exit site beginning in the center and continuing outward 2 inches in a concentric circle." An illustration was included with the instructions.</p> <p>The CDC publication titled Basic Infection Control and Prevention Plan - Changing Catheter Site Dressing, dated 2011, included instructions to "maintain aseptic technique."</p>	V 112		3/7/16

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V 112	Continued From page 2 During an observation on 1/26/16 from 8:00 - 11:00 a.m., the following was noted: Patient #4 was being prepared for dialysis using a CVC. Staff removed the old CVC exit site dressing. Staff then used two disinfectant swabs to clean the exit site and surrounding skin. A random scrubbing motion was used, with staff frequently moving the swab from the outside of the concentric circle inward to the exit site, contaminating the already cleaned area. In an interview on 1/29/16 at 9:00 a.m., the Nurse Manager confirmed staff should have followed facility policy and procedure by swabbing from the exit site outward.	V 112			
V 403	The facility failed to follow infection control precautions when caring for Patient #4. 494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This STANDARD is not met as evidenced by: Based on staff interview, equipment log review, facility policy review, and manufacturer's recommendation review, it was determined the facility failed to ensure dialysis machines were maintained in accordance with the manufacturer's recommendations for 3 of 7 machines (machines #716, #784, and #023) used at the facility. This	V 403		2/20/16	

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V 403	<p>Continued From page 3</p> <p>failure had the potential to impact all patients at the facility by receiving dialysis treatments with potentially faulty equipment. Findings include:</p> <p>The facility used 7 Fresenius 2008T dialysis machines to perform hemodialysis treatments for 31 patients. Each machine was assigned an identifying number and maintenance records were kept according to the machine's assigned number.</p> <p>Facility Policy titled Fresenius Criteria for Preventive Maintenance (#153-060-010), dated 7/15/1994, stated all dialysis equipment maintenance "will be in accordance with the manufacturer's printed recommendations."</p> <p>The undated maintenance manual for Fresenius 2008T machines, Part 508033 Revision F, stated a 6 month/semi annual PM procedure should be performed "every 6 months of machine operation." The manual also stated an annual PM procedure should be performed "every 12 months or 4000 hours of operation, whichever comes first."</p> <p>The facility machine maintenance logs were reviewed. Documentation of PM could not be found, as follows:</p> <p>Machine #784 did not have documentation of annual PM, which was due in August, 2015.</p> <p>Machine #023 did not have documentation of 6 month PM, which was due in December, 2015.</p> <p>Additionally, Machine #716 had documentation of an annual PM performed 11/24/15, one month after it was due.</p>	V 403			

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V 403	Continued From page 4	V 403			
V 463	<p>In an interview on 1/27/16 at 6:30 p.m., the facility's ATOM confirmed the missing PM documentation. At that time four patients were receiving hemodialysis in the facility. As the patients completed their treatments, the ATOM and another biomedical technician immediately perform preventive maintenance.</p> <p>The facility failed to ensure hemodialysis machines were maintained according to manufacturer's recommendation.</p> <p>494.70(a)(12) PR-RECEIVE SERVICES OUTLINED IN POC</p> <p>The patient has the right to-</p> <p>(12) Receive the necessary services outlined in the patient plan of care described in §494.90;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the facility failed to ensure patients' rights to receive care as outlined in their POCs were upheld. This directly impacted 11 of 22 ICHD patients (Patients #2 and #5 - #14) who had current Calcitriol prescriptions. This failure left patients at risk of decreased serum calcium levels and resulting complications. The findings include:</p> <p>Calcitriol (an oral Vitamin D analog) was supplied to the facility by a pharmaceutical vendor in 0.5 mcg tablets and 0.25 mcg tablets. These tablets were administered to patients, alone or in combination, to satisfy different dosages</p>	V 463		2/29/16	

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V 463	<p>Continued From page 5</p> <p>prescribed for patients at the facility. During the time period 1/5/16 - 1/18/16 eleven patients did not receive prescribed doses of the medication, due to the unavailability of Calcitriol 0.25 mcg tablets in the facility, as follows:</p> <p>a. Patient #2 was prescribed 1.25 mcg of Calcitriol on 1/11/16, to be given orally during each dialysis treatment. This would have been administered as two 0.5 mcg tablets and one 0.25 mcg tablet. Documentation showed Patient #2 received no Calcitriol during her 1/15/16 and 1/18/16 dialysis treatments.</p> <p>b. Patient #5 had a current order for Calcitriol 0.25 mcg to be given orally during each dialysis treatment. She received no Calcitriol during treatments on 1/8/16, 1/11/16, and 1/13/16.</p> <p>c. Patient #6 had a current order for Calcitriol 0.25 mcg to be given orally during each dialysis treatment. He did not receive Calcitriol during treatments on 1/8/16, 1/11/16, and 1/13/16.</p> <p>d. Patient #7 had a current prescription for Calcitriol 0.75 mcg to be given orally during each dialysis treatment. This would have been administered as one 0.5 mcg tablet and one 0.25 mcg tablet. She did not receive Calcitriol during her treatment on 1/18/16.</p> <p>e. Patient #8 had a current order for Calcitriol 0.25 mcg to be given orally during each dialysis treatment. She received no Calcitriol during her 1/9/16, 1/12/16, and 1/14/16 treatments.</p> <p>f. Patient #9 had a current order for Calcitriol 0.25 mcg to be given orally during each dialysis treatment. He did not receive Calcitriol during his</p>	V 463			

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V 463	<p>Continued From page 6 treatments on 1/5/16 and 1/9/16.</p> <p>g. Patient #10 had a current order for Calcitriol 1.25 mcg to be given orally during each dialysis treatment. This would have been administered as two 0.5 mcg tablets and one 0.25 mcg tablet. He received no Calcitriol during his 1/14/16 treatment.</p> <p>h. Patient #11 had a current order for Calcitriol 0.25 mcg to be given orally during each dialysis treatment. He received no Calcitriol during his 1/11/16 and 1/13/16 treatments.</p> <p>i. Patient #12 had a current order for Calcitriol 0.25 mcg to be given orally during each dialysis treatment. No Calcitriol was administered to Patient #12 during treatment on 1/12/16.</p> <p>j. Patient #13 had an order for Calcitriol 0.25 mcg to be given orally during each dialysis treatment. She received no Calcitriol during her 1/8/16 treatment.</p> <p>k. Patient #14 had a current order for Calcitriol 0.25 mcg to be given orally during each dialysis treatment. He received no Calcitriol during his 1/8/16 treatment.</p> <p>In an interview on 1/29/16 at 8:30 a.m., the Nurse Manager explained Calcitriol was ordered from a pharmaceutical vendor using a scanning process. She said she had ordered, but not received, Calcitriol 0.25 mcg tablets several times. On or about 1/5/16, the facility supply of Calcitriol was critically low. She called the vendor and was told the incorrect scanning code had been used. On approximately 1/8/16 the correct scanning code was used to order the Calcitriol to be delivered via</p>	V 463		

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V 463	Continued From page 7 overnight shipment. The medication had not arrived at the facility by 1/14/16, at which time the Nurse Manager again contacted the vendor and was told the medication had been delivered to the hospital pharmacy next door. The hospital shared the same address as the facility. Upon investigation it was found the hospital pharmacy, not having ordered Calcitriol for their own stock, had returned the medication to their own supplier. The Nurse Manager ordered Calcitriol 0.25 mcg tablets on 1/14/16 for overnight delivery. It was received on or about 1/15/16. During the same interview, as well as during a telephone interview on 2/1/16 at 11:30 a.m., the Nurse Manager confirmed eleven facility patients did not receive their prescribed Calcitriol during this time period due to the unavailability of the 0.25 mcg tablets.	V 463			
V 625	The facility failed to ensure patients received prescribed treatment medications. 494.110 CFC-QAPI This CONDITION is not met as evidenced by: Based on staff interview and QAPI meeting minutes review, it was determined the facility failed to ensure an effective QAPI program was maintained that recognized and corrected problems affecting patients' health. The failure to perform regular PMs had the potential to negatively impact patients in the event that an unidentified machine malfunction occurred. Findings include: Refer to V626 as it relates to the facility's failure	V 625		2/22/16	

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V 625	Continued From page 8	V 625		
V 626	to ensure technical personnel presented accurate data to the QAPI committee for review. 494.110 QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS. This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI documents and dialysis machine logs, it was determined the facility failed to ensure an effective, data-driven quality assessment and performance improvement program was implemented and maintained. This prevented the facility from analyzing biomedical department activities and limited the facility's ability to correct deficiencies in machine maintenance. Findings include: 1. The facility used 7 Fresenius 2008T dialysis machines to perform hemodialysis treatments for 31 patients. Each machine was assigned an identifying number and maintenance records	V 626		

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V 626	<p>Continued From page 9</p> <p>were kept according to the machine's assigned number.</p> <p>Facility Policy titled Fresenius Criteria for Preventive Maintenance (#153-060-010), dated 7/15/1994, stated all dialysis equipment maintenance "will be in accordance with the manufacturer's printed recommendations."</p> <p>The maintenance manual for Fresenius 2008T machines, Part 508033 Revision F, stated a 6 month/semi annual PM procedure should be performed "every 6 months of machine operation." The manual also stated an annual PM procedure should be performed "every 12 months or 4000 hours of operation, whichever comes first."</p> <p>A review of facility machine maintenance logs was started on 1/27/16 at 11:00 a.m. Review was stopped to allow for the placement of unfiled documentation. Review resumed at 6:00 p.m. on 1/27/16. At that time, six of seven dialysis machines used for treatments at the facility were not in compliance with manufacturer's recommendation and facility policy as follows:</p> <p>Machine #354 did not have documentation of an annual PM done when due in July, 2015.</p> <p>Machine #669 did not have documentation of an annual PM done when due in September, 2015.</p> <p>Machine #716 had documentation of an annual PM performed 11/24/15, one month after it was due.</p> <p>Machine # 748 did not have documentation of a 6 month PM done when due in June, 2015.</p>	V 626			

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

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FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 132515	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 02/01/2016
NAME OF PROVIDER OR SUPPLIER IDAHO KIDNEY CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 98 POPLAR STREET BLACKFOOT, ID 83221		
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V 626	<p>Continued From page 10</p> <p>Machine #784 did not have documentation of an annual PM done when due in August, 2015.</p> <p>Machine #023 did not have documentation of a 6 month PM done when it was due in December, 2015.</p> <p>The ATOM and another biomedical technician were notified of the missing maintenance records on 1/27/16 at 6:30 p.m. The facility's ATOM confirmed the missing PM documentation for six machines. He said the facility biomedical department had a corporate computer system with a feature that alerted the technician when machines were due for maintenance. However, when asked, he said there was no system in place for auditing whether or not the maintenance was completed.</p> <p>At the time the missing PM records were identified, four patients were receiving hemodialysis in the facility. As the patients completed their treatments, the ATOM and another biomedical technician immediately perform preventive maintenance. Additional PM was performed necessary to ensure all six identified machines were current as of 1/27/16.</p> <p>The following day, 1/28/16, documentation of preventive maintenance for machines #354 (dated 7/12/15), #669 (dated 9/17/15), and #748 (dated 6/30/15) was delivered to the facility.</p> <p>However, no documentation related to machines #716, #784, and #023 was found.</p> <p>Minutes of the QAPI committee's activities were reviewed from January, 2015 - December, 2015.</p>	V 626		

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V 626	<p>Continued From page 11</p> <p>An area specific to hemodialysis machine maintenance was found under the title Preventive Maintenance, with the question "Dialysis Machine PMs complete per policy and as scheduled?" This question was answered "yes" for 11 of 12 months. The exception was October, 2015 when no information had been submitted relative to dialysis machine PMs.</p> <p>This information was compared to the facility's machine maintenance logs and did not reflect accuracy of the QAPI data submitted. The data submitted to QAPI for review and analysis did not show a missed annual PM for machine #784 due in August, 2015. The data did not show a missed 6 month PM for machine #023 due in December 2015. The data did not show a late annual PM for machine #716 due in October, 2015 and performed in November, 2015.</p> <p>The inaccuracy of submitted data prevented the QAPI committee from initiating an action plan to prevent missed machine PMs in the future.</p> <p>When asked on 1/28/16 at 5:30 p.m., the ATOM said he reviewed the summary data information submitted to the QAPI committee but did not routinely review machine logs. He said individual machine logs were reviewed during annual facility audits. He confirmed the discrepancies noted between machine logs and submitted QAPI data for machines #716, #784, and #023.</p> <p>The facility failed to ensure accurate data was submitted to the QAPI committee for review and potential action.</p>	V 626			

V112 494.30 (a) IC-CDC MMWR 2001

The Clinical Manager in-serviced facility staff on policy and procedure FMS-CI-IC-I 105-032 Changing the Catheter Dressing on 2/3/16. By March 7 2016 the facility RN Educator will in-service staff on the facility procedure as well

Beginning the week of 2/8/16 the Clinical Manager and/or Charge RN will perform Central Venous Site exit site care audits on each nurse weekly for two weeks. These observation will present opportunities to ensure facility staff is following proper procedure.

The Clinical Manager will present the results of the audits at the weekly Governing Body for review. Based on the results of the audits the Governing Body will determine the frequency of the audits.

The Clinical Manager or designee will provide ongoing monitoring utilizing the QAI CVC infection control audits. These audits will be completed according to the QAI calendar.

Clinical Manager will present in QAI the results of all audit reports and monitoring as related to this Plan of Correction to the monthly QAI Committee for review and oversight.

The Medical Director is to review the results presented at the QAI meeting and documented activity is appropriate for the deficiency, intervention is effective and that resolution is noted.

The Director of Operations is responsible to present the status of the Plan of Correction with documentation as appropriate to the Governing Body on an ongoing basis until all issues related to the citations have been corrected and ongoing resolution is noted.

V403 494.60 (b) PE-Equipment Maintenance-Manufacturers DFU

Initial Governing Body meeting held 2/2/16 to discuss and develop a process for correcting deficiencies from exit call. Once SOD received Governing Body will meet weekly until deficiencies are resolved.

On 2/4/16 the Area Technical Operations Manager re-educated the Biomed on Policy 153-060-010 Fresenius Criteria for Preventive Maintenance.

100% of all hemodialysis machines were audited by Biomed for current PM documentation. All machines missing documentation had PM completed. Date completed 1/27/16.

Hemodialysis Machine PM schedule will be reviewed and updated on 1/27/16 by the Area Technical Operations Manager if necessary.

Beginning February 2016 Biomed will present prior to the QAI meeting the previous months PM(s). Documentation will be supplied to RTOM/ATOM/CM/Director of Operations to confirm accurate reporting in QAI and initiate plan as needed.

On 2/16/16 RTOM will re-educate the Biomed on the requirements for documenting PM's completed on Preventive maintenance log and QAI reporting requirements. If employee performance does not improve it will be reported to the ATOM for possible corrective action.

Director of Operations will re-educate the Clinical Manager on the QAI process by 2/11/16.

Re-education of QAI process with Blackfoot Interdisciplinary team staff will be provided by the Director of operations on 2/9/16.

On 2/9/16 Director of Operations will review the interdisciplinary team the conditions for coverage requirements, FMC QAI process and policies and workbooks and tools for assisting with trending and identifying deficiencies.

The Medical Director is to review the results presented at the QAI meeting and documented activity is appropriate for the deficiency, intervention is effective and that resolution is noted.

The Director of Operations is responsible to present the status of the Plan of Correction with documentation as appropriate to the Governing Body on an ongoing basis until all issues related to the citations have been corrected and ongoing resolution is noted.

V463 494.70(a) (12) PR-Received services outlined in POC

On 2/20/16 Administrative Assistant confirmed correct shipping address with AmerisourceBergen.

Clinic Manager will review medication ordering process on 2/29/16 with ward clerk and biomed technicians. Software programs and ordering devices will also be reviewed in this process to confirm competency.

Beginning 2/29/16 the Clinic Manager will increase the amount of medication on-hand to avoid all instances of a shortage in medication.

Beginning 2/1/16 the Clinical Manager or designee will establish an average timetable for medications to arrive at the facility. If medications run past the average timetable the Administrative Assistant will start to track shipment.

Clinic Manager will perform monthly inventory counts assessing the need for additional medication. If a low count is identified a medication orders will placed immediately.

V625 494.110 CFC-QAPI

The Governing Body of this facility understands its requirement to ensure that the facility maintains an effective Quality Assessment and Performance Improvement program that identifies opportunities for improvement to include:

- Continuously monitoring performance of the facility
- Taking action that result in performance improvement
- Track and trend performance to ensure that improvements are sustained over time.

- Documenting a review of the trends for prevalence of occurrences and causes for including but not limited to;
 - Preventive Maintenance on Hemodialysis Machines
 - Preventive Maintenance log completion

By (2/17/16) the Regional Vice President (RVP) will meet with the Director of Operations (DO) to review and reinforce the DO's responsibilities to serve as Chairperson of the QAPI Committee and ensure that all areas of the QAPI as defined within the 2016d QAPI Program are complete, current per the QAPI calendar and provide evidence for analysis and trending. It is the role of the DO to ensure all data is presented per the schedule, is reviewed, trends identified and a root cause analysis completed with the development and implementation of a Plan of Action as appropriate and resolution is ongoing

By (2/11/16), the Director of Operations will meet with the Clinical Manager to review and reinforce the Clinical Managers responsibilities to ensure all issues related to the QAPI program including those defined within the Plan of Correction, have been audited and reviewed. The data will be analyzed, trended, prioritized and presented for the QAPI committee oversight to include reporting of adverse events and their entry into the Medical Information System.

By (2/16/16), the Governing Body (GB) will meet with the members of the QAPI committee to participate in education of the QAPI program scope and requirements emphasizing the requirement for collection of data on the QAPI clinical indicators, Hemodialysis Machine Preventive Maintenance documentation and the development and follow through of action plans as they are documented. The requirement to identify opportunities to improve performance will be reviewed. The QAPI in-service will be completed by (2/16/16).

Effective Immediately

- The Clinical Manager and or the Director of Operations will analyze and trend all data and monitoring/audit results as related to this plan of Correction prior to presenting the monthly data to the QAPI Committee.
- A specific plan of action encompassing the citations as cited in the Statement of Deficiencies has been added to the facility's monthly QAPI agenda.
- The QAPI committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of the issues.
- The Regional Vice President will be invited to attend Governing Body meetings either in person or via telephone.
- The Director of Operations will attend each Governing body and QAPI meeting, either in person or via the telephone. His role is to provide oversight to the QAPI Committee to ensure that all aspects of the POC as related to the QAPI are in place and effective in resolving the deficiency.
- The Governing Body, through its ongoing monitoring of the QAPI Committee, will ensure the immediate and ongoing identification of potential and actual problems to patient care and take appropriate steps to identify the root causes and to develop, implement and track corrective actions through to resolution.

Any issues/problems will be addressed within the QAPI via steps as noted throughout the POC, documented in the QAPI minutes, and formally reported to the Governing Body. Minutes of the Governing Body and QAPI meetings, as well as, monitoring forms, educational documentation will provide evidence of these actions, the GB's direction and oversight and the QAPI Committees ongoing monitoring of the facility's activities. These are available at the facility for review.

The responses provided in V626 describe in detail the processes and monitoring steps that have been implemented to ensure all deficiencies have been addressed to ensure ongoing resolution of each issue.

V626 494.110 QAPI-Covers Scope serv/effective/IDT invol

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