

COPY



IDAHO DEPARTMENT OF
HEALTH & WELFARE

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

DEBRA RANSOM, R.N., R.H.I.T., Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
P.O. Box 83720
Boise, ID 83720-0009
PHONE 208-334-6626
FAX 208-364-1888

CERTIFIED MAIL: 7007302000140387648

January 18, 2013

Clinton Fairless, Administrator
North Idaho Dialysis Unit
2100 Ironwood Court
Coeur D'Alene, ID 83814

RE: North Idaho Dialysis Unit, Provider #132507

Dear Mr. Fairless:

Based on the survey completed at North Idaho Dialysis Unit, on January 11, 2013, by our staff, we have determined North Idaho Dialysis Unit is out of compliance with the Medicare ESRD Conditions for Coverage of **Patient Plan of Care (42 CFR 494.90) and Quality Assurance/Performance Improvement (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 North Idaho Dialysis Unit, 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;
- 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

Clinton Fairless, Administrator
January 18, 2013
Page 2 of 2

- 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 February 25, 2013. 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 February 15, 2013.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **January 31, 2013.**

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.

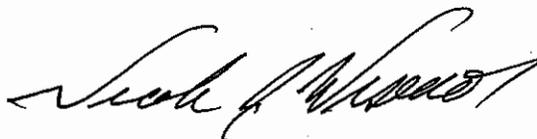
We urge you to begin correction immediately.

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

Sincerely,



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



NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

TO/nw
Enclosures

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



Fresenius Medical Care

January 30, 2013

RECEIVED

JAN 31 2013

Debra Ransom, RN.,R.H.I.T., Chief
Bureau of Facility Standards
Idaho Department of Health and Welfare

FACILITY STANDARDS

Re: North Idaho Dialysis Unit
CMS Certification Number (CCN): 132507

Dear Ms Ransom,

This letter is in response to the Centers for Medicare & Medicaid Services letter to facility management dated January 18, 2013 regarding serious deficiencies at the North Idaho Dialysis Unit. It is to provide credible allegation that deficiencies cited as a result of the January 11, 2013 facility survey have been corrected and that the facility is in full compliance with Part 494 Conditions for Coverage. As such, I request the Department review the following description of corrective actions and determine to afford the facility an additional revisit to verify compliance and halt the termination process.

The corporate and field management of the North Idaho Dialysis Unit and Fresenius Medical Care-North America take seriously their responsibility to ensure that the North Idaho Dialysis Unit Governing Body demonstrates responsibility for all operations of the facility including:

- Operationalizing all policies and procedures related to "Plan of Care" to ensure that patients receive the necessary services outlined in the Plan of Care.
- The immediate retraining and operationalizing of all policies and procedures and processes to ensure each patient's plan of care is revised to address the appropriate access for each patient.
- Ensure that the facility's Quality Assessment and Improvement Program is continuously monitored to ensure the delivery of quality care and address extended CVC use and hospitalization rates to improve results.
- Working directly with the Medical Director to ensure policies and procedures are adequate and up to date.

The Governing Body has implemented the following processes to correct these citations to ensure ongoing compliance.

- The Governing Body is meeting weekly until the Condition status is cleared, then monthly for three months then returning to a quarterly basis when ongoing resolution of the issues has been verified.
- The Clinical Manager is analyzing and trending all data and reviewing audit results as related to this Plan of Correction prior to presenting the monthly data to the QAPI Committee for oversight and review.
- The Clinical Manager is presenting a report on the Plan of Correction data and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the resolution of all identified issues.
- A specific plan of action encompassing the deficiencies as cited in the Statement of Deficiency has been added to the facility's monthly QAPI (Quality Assessment and Performance Improvement) Agenda. The QAPI Committee is reviewing and evaluating the Plan of Correction to ensure its effectiveness in providing resolution of the issues.
- The Governing Body has approved and committed to the processes defined within this POC and is reviewing the outcomes at each GB meeting ensuring resolution of noted deficiencies specific to the citations noted within the Statement of Deficiency.

Fresenius Medical Care North America ♦ Dialysis Services

Intermountain Region – Idaho Area
2100 Ironwood Drive, Coeur d'Alene, ID 208.664.3064 Fax: 208.664.1353



Fresenius Medical Care

- Minutes of the Governing Body and QAPI meetings provide evidence of these actions, the Governing Body's direction and monitoring of facility activities. These are available for review in the facility.

Further specific details related to all of these individual deficiencies, subsequent monitoring and presentation to the QAPI Committee for oversight, are presented in detail in the attached Plan of Corrections.

I believe that, as a result of the changes made through the Governing Body actions, the development and implementation of the above described corrective actions, processes and monitoring systems, as well as the company's local, regional and corporate support for facility operations; the North Idaho Dialysis Unit is operating in compliance with the Conditions for Coverage as put forth in Part 494 of the Federal Regulations. I therefore request, as noted above, that CMS direct that the facility be afforded an opportunity, in the form of a revisit, to demonstrate its compliance.

If you have questions, I can be reached at 208-664-3064. I look forward to your response regarding the above stated requests and thank you for your consideration.

Sincerely,

Marta Urbaniak
Clinical Manager
North Idaho Dialysis Unit, Fresenius Medical Care: North Idaho Area

Cc:

Tom Sisung, Regional Vice President – Intermountain Region
Monica Cobb, Group Vice President, Western Skies Group – FMCNA West Division
Brenda Britos, Regional Quality Manager (RQM) – Intermountain Region
Cindy Albrecht, Vice President Quality – FMCNA West Division

North Idaho Dialysis Unit
Plan of Correction
Date of Survey: 01/11/2013

V463:494.70(a)(12) PR-RECEIVE SERVICES OUTLINED IN POC

On 01/14/13, the Medical Director, Area Manager, Clinical Manager, Regional Quality Manager, Regional Director of Education, Education Coordinator, Lead Social Worker and Biomedical met to discuss the findings and institute correction of the deficiency related to the facility's failure to ensure patients' rights to receive care as outlined in their POC was upheld.

As a result of this meeting and to address the findings from the January 11th survey, the following actions have occurred:

1. On 01/22/13, mandatory staff meetings were held at the facility. The Clinical Manager provided re-education and expectation for staff compliance on the following facility policies:
 - a. Early Termination or Arriving Late for Treatment Policy (FMS-CS-IC-I-110-144A)
 - b. Early Termination of Treatment Against Medical Advice (FMC-CS-IC-I-110-144D1)
2. To reinforce expectation of mandatory compliance, the Clinical Manager has scheduled additional education to be completed no later than 01/30/13, on the following facility policies:
 - a. Interruption of Treatment (FMS-CS-IC-I-105-024A)
 - b. Interruption of Treatment Procedure (FMS-CS-IC-I-105-024C)

Additionally, in the event that deviation from the prescribed treatment time is imminent the assigned nurse is responsible to assess the patient, determine root cause and notify the patient's Nephrologist who may determine to arrange for additional dialysis.

To monitor for compliance, the Clinical Manager has implemented the following review process:

1. Beginning 1/24/2013, the Clinical Manager or assigned designee is auditing 100% of the daily treatment sheets for compliance to physician orders as prescribed. This review identifies but is not limited to:
 - a. Patients with run times less than prescribed with referral to the assigned nurse.

- b. Nursing assessment of the patient to identify root cause of noncompliance, applied nursing intervention and if warranted physician notification.

The Clinical Manager ensures compliance by monitoring the treatment sheets daily, addressing identified discrepancies with the assigned nurse documenting findings on the facility treatment sheet audit tool. Upon determination of compliance by the Governing Body, the audit will decrease the following increments:

- a. Daily for four weeks
- b. Weekly for four weeks

The Clinical Manager is responsible to review, analyze and trend the results of all audits and present to the QAI Committee for review and oversight. Monitoring of corrections will be discussed monthly with the Area Manager and Medical Director at the Quality Assessment and Improvement meeting beginning January 2013.

Meeting minutes will document the activity and will be available for review at the facility. The Clinical Manager is responsible and the QAI monitors for compliance.

Completion Date: 02/15/2/13

V516:494.80(b)(1) PA-FREQUENCY-INITIAL-30DAYS/13 TX

On 01/14/13, the Medical Director, Area Manager, Clinical Manager, Regional Quality Manager, Regional Director of Education, Education Coordinator, Lead Social Worker and Biomedical met to discuss the findings and institute correction of the deficiency related to the facility's failure to ensure a comprehensive initial assessment was completed within 30 days or 13 treatments of the initiation of dialysis for 1 of 3 patients.

To specifically address the patient identified as lacking a completed Comprehensive Patient Reassessment the following actions have occurred:

1. On 01/15/13, the IDT completed a comprehensive reassessment on the patient identified as #12.
2. On 01/25/13, an audit of the patient comprehensive assessment of each patient was completed with no identified deficiencies.
3. On 01/25/13, the facility Comprehensive Assessment and Plan of Care tickler file was updated with each patient's CIA/POC due date.

The Clinical Manager prepares a formal report of those patients whose plan of care was due for completion but lacked completion by all team members, along with any applied intervention to correct the deficiency, at each month's QAI meeting.

The QAI Committee addresses any discrepancy/variance to the required process by identifying an opportunity for improvement of the problematic process/outcome and will investigate to determine the root cause. Once the root cause has been identified, the Committee will develop, implement and track a corrective action plan through to resolution of the issue. QAI Minutes as described above – will document these actions and will be available for review at the facility

The Clinical Manager is responsible and the QAI Committee monitors for compliance.

Completion Date: 02/15/2/13

V540:494.90 CFC-PATIENT PLAN OF CARE

As a result of the citations from the January 11, 2013 survey and as part of the developed plan of correction, the Governing Body has implemented corrective measures described in a brief summary below and in greater detail in the reference V-tag.

1. Reinforced, reeducated and implemented a monitoring process to ensure each patient's plan of care is revised to address the appropriate access for each patient. Please refer to V-550

V550:494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS

1. On 01/22/13, mandatory staff meetings were held at the facility. The Clinical Manager provided re-education and expectation for the IDT and staff compliance on the following facility policies:
 - a. Hemodialysis Catheter Patient Access Plan Policy
FMS-CS-IC-I-115-016A
 - b. Hemodialysis Catheter Patient Access Plan Procedure
FMS-CS-IC-I-115-016C
 - c. Hemodialysis Catheter Patient Access Plan
FMS-CS-IC-I-115-016D1
 - d. Informed Refusal to Discontinue use of a Hemodialysis Catheter Form

As a result of this meeting the following corrective action has occurred:

1. On 01/29/13, the Governing Body appointed a vascular access nurse who is responsible to:
 - a. Maintain the patient vascular access action plan on each patient with a CVC access
 - b. Maintain the vascular access tracking tool

- c. Update each patient medical record with current vascular access history reports, inclusive of patients identified as numbers 6,11,14 and 15.
- d. Ensure the review of each patient vascular access plan with the assigned physician during patient rounds and at the patient plan of care meeting until such time as the CVC is removed. In the event that an alternative access is contraindicated, the access review will revert to the routine CIA/POC review schedule.
- e. Participate at the 01/30/13 patient plan of care meeting to discuss, review and include Interdisciplinary Team inclusion in the patient plan of care a plan to encourage placement and use of an AVF/AVG access.

The vascular access nurse summarizes the status of catheter reduction program along with any related issues for monthly for presentation at the facility QAI meeting. Ongoing monitoring will occur through monthly scheduled QAI Access Review per the calendar.

The Clinical Manager is responsible to review, analyze and trend the results of all audits and present to the QAI Committee for review and oversight.

Monitoring of corrections will be discussed monthly with the Area Manager and Medical Director at the Quality Assessment and Improvement meeting beginning January 2013.

Meeting minutes will document the activity and will be available for review at the facility.

Completion Date: 02/15/2/13

V625:494.110 CFC-QAPI

As a result of the citations from the January 11th survey and as is the commitment of the Medical Director of this facility to ensure that its Quality Assessment Improvement program is continuously monitored to ensure the delivery of quality care, immediately following the exit interview the Governing Body consulted with the Medical Director and as a result determined to:

1. Educate all QAI Team members to the QAI process inclusive of requirements to analyze vascular access and infection data, develop and implement a QAI action plan to address extended CVC use and hospitalization rates for septicemia related to the CVC use. Please refer to V 627

The Clinical Manager is responsible to monitor, document and report on the implemented action plan directly to the Medical Director, Area Manager and to formalize a written report to the QAI committee. If sufficient progress to correct the identified deficiencies in not met, the QAI committee will direct the revision of the action plan until resolution is achieved.

The Clinical Manager is responsible and the QAI committee which the Medical Director leads, monitors for compliance

V627:494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT

On 01/30/13, the Regional Quality Manager met with participants of the QAI committee for the purpose of reeducation on the QAI process related to the development and implementation of action plans to address extended CVC use and hospitalization rates for septicemia related to CVC use. This education will include but not limited to the following:

- a. Quality Assessment and Performance Improvement Program Policy (FMS-CS-IC-I-101-001A)
- b. 2013 QAI Program, Tools and Minutes requirements
- c. Tracking, trending and analyzing data for the purposes of developing action plans for areas of concern.
- d. Reviewing mechanism for identification and correction of infections

As a result of this meeting, the QAI committee has taken the following actions:

- a. Reviewed the survey dated January 11, 2013 along with trending tools documenting areas as in need of improvement with the development of an improvement plan.
- b. Presented findings with follow up discussion documented in the 01/29/13 QAI meeting minutes for those indicators in need of improvement or documentation of resolution if so warranted.
- c. Developed a formal QAI action plan to address extended central venous catheter use and hospitalization related to infection inclusive of the previous six month history of facility hospitalizations
- d. Appointed the facility Clinical Manager to present the action plan at each monthly QAI meeting revising the plan monthly until the facility goals are met

To ensure the QAI committee prioritizes improvement and as part of the developed plan of correction, the Governing Body has determined to review QAI activities monthly until full resolution of the implemented corrective processes is verified and quarterly thereafter.

To ensure that expected compliance is achieved as outlined in the developed plan of correction, the Governing Body determined that the Clinical Manager will formalize a report for the scheduled Governing Body meeting detailing compliance gaps, action taken to correct deficiencies. If sufficient progress to correct the identified deficiencies is not met, the Governing Body directs the revision of the action plan until resolution is achieved

The Clinical Manager is responsible and the QAI committee monitors for compliance.

Completion Date: 02/15/2/13

V714:494.150(c)(1) MD RESP-DEVELOP, REVIEW & APPROVE P &P

On 01/14/13, the Medical Director, Area Manager, Clinical Manager, Regional Quality Manager, Regional Director of Education, Education Coordinator, Lead Social Worker and Biomedical met to discuss the findings and institute correction of the deficiency related to the facility's failure to ensure policies and procedures were adequate and up to date. As a result of this meeting and to correct the cited deficiency, the following actions have occurred:

1. On 01/29/13, the Governing Body reviewed the adoption and implementation of the following facility policies:
 - a. Assessment and Cannulation of a New AV Fistula Policy (FMS-CS-IC-I-115-015A)
 - b. Assessment and Cannulation of a New AV Fistula Procedure (FMS-CS-IC-I-115-015C)
 - c. Implementation Process for the Facility Assessment and Cannulation Plan
2. On 01/22/13, mandatory staff meetings were held at the facility. The Clinical Manager provided re-education and expectation for staff compliance on the following:
 - a. Assessment and Cannulation of a New AV Fistula Policy (FMS-CS-IC-I-115-015A)
 - b. Assessment and Cannulation of a New AV Fistula Procedure (FMS-CS-IC-I-115-015C)

Further and as part of the developed QAI action plan developed to address reduction of central venous catheters and related infection in this facility, the Medical Director approved the implementation of the facility access assessment and cannulation plan.

The Clinical Manager is responsible to summarize and report the progress of the plans effectiveness during each scheduled Governing Body meeting. To ensure the effectiveness of the plan, the Medical Director has committed to weekly Governing Body meetings to ensure the full implementation of the corrective actions until the conditions are lifted at which time the Governing Body will meet monthly until the Governing Body determines the full resolution of the identified deficiencies.

Additionally, the Clinical Manager summarizes her findings to the QAI committee which the Medical Director chairs. The committee analyzes the data and determines if further action is warranted and following up as it determines is necessary. All reported events are evaluated for trends, and corrective and/or preventative measures implemented as warranted.

The committee may recommend procedural or operational changes that are required to prevent reoccurrence of significant events. Target dates for implementation should be included. QAI minutes document this activity and will be available for review at the facility.

The Clinical Manager is responsible and the Medical Director as chair of the QAI committee monitors to ensure on-going compliance.

Completion Date: 02/15/2/13

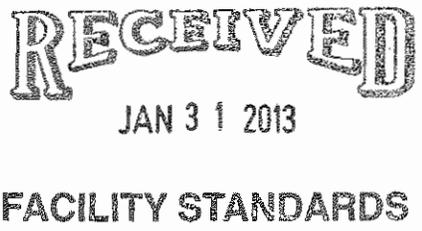
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 01/18/2013
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 132507	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 01/11/2013
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NAME OF PROVIDER OR SUPPLIER NORTH IDAHO DIALYSIS UNIT	STREET ADDRESS, CITY, STATE, ZIP CODE 2100 IRONWOOD COURT COEUR D'ALENE, ID 83814
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(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
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V 000	INITIAL COMMENTS The following deficiencies were cited during the recertification survey of your ESRD facility. The surveyor conducting the survey was: Trish O'Hara, RN Acronyms used in this report include: AVF - Arterial Venous Fistula AVG - Arterial Venous Graft BFR - Blood Flow Rate CVC - Central Venous Catheter DRIL - Distal Revascularization - Interval Ligation IDT - Interdisciplinary team P&P - Policy and Procedure PCT - Patient Care Technician POC - Plan of Care QAPI - Quality Assurance Performance Improvement RN - Registered Nurse	V 000	 See attached	
V 463	494.70(a)(12) PR-RECEIVE SERVICES OUTLINED IN POC The patient has the right to- (12) Receive the necessary services outlined in the patient plan of care described in §494.90; This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the facility failed to ensure patients' rights to receive care as outlined in their POC was upheld for 3 of 6 incenter hemodialysis patients (Patients #1, #5 and #6) whose treatment records were reviewed. This resulted in patients being left at risk for	V 463		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE M. Urbanik, RN TITLE Clinical Manager (X6) DATE 1/30/13

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.

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V 463	<p>Continued From page 1</p> <p>complications of inadequate dialysis and fluid overload. Findings include:</p> <p>1. Patient #6 was a 75 year old female whose dialysis prescription included an ordered treatment time of 3 hours, two times a week.</p> <p>During an observation on 1/8/13 from 2:00 - 4:00 PM, Patient #6 was disconnected from the dialysis machine and left the treatment floor to use the restroom. She was gone from the dialysis station for approximately 20 minutes. The machine was paused during this time. At approximately 3:20 PM a conversation was noted between a PCT and the RN. The RN told the PCT if a patient's treatment was interrupted for the patient to use the restroom, their treatment time "should always be cut." The RN then approached Patient #6 and discontinued her treatment with time remaining on the dialysis machine clock. The RN told Patient #6 that her treatment was being cut short due to her bathroom break and also told Patient #6 that her transportation was waiting in the lobby. Patient #6 was not offered the opportunity to make up the lost time. Patient #6 was observed to wait in the lobby for her transportation until 4:00 PM.</p> <p>In an interview on 1/8/13 at 4:15 PM, the PCT was asked what facility policy stated concerning shortening patient treatments as a result of a bathroom break. He stated he did not know what policy was and he always deferred to the RN to make the decision.</p> <p>In an interview on 1/8/13 at 4:20 PM, the RN stated it was the "general consensus" of RNs, company wide, that patient treatments were to be</p>	V 463		
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V 463	<p>Continued From page 2</p> <p>shortened if time off the machine was taken to use the restroom.</p> <p>Additionally, the records of Patient #1 and Patient #5 were reviewed and documented the following:</p> <p>a. Patient #1 was a 40 year old male whose dialysis prescription included an ordered treatment time of 4 hours, three times a week. Thirteen treatment sheets were reviewed, from 12/1/12 - 1/5/13, for Patient #1. Shortened treatment times were noted as follows:</p> <p>12/20/12: 3 hours 18 minutes 12/22/12: 2 hours 22 minutes 12/29/12: 3 hours 32 minutes 1/5/13: 3 hours 53 minutes</p> <p>This reflected a loss of 175 minutes of dialysis time for Patient #1 during a one month period. A nursing note stated Patient #1 was offered and refused to reschedule 98 minutes lost on 12/22/12 due to an infiltration. However, no documentation was present to indicate Patient #1 was offered the opportunity to reschedule a cumulative 77 minutes of dialysis time lost on 12/20/12, 12/29/12, and 1/5/13.</p> <p>b. Patient #5 was a 43 year old male whose dialysis prescription included a treatment time of 3.5 hours, three times a week. Twelve treatment sheets were reviewed, from 12/1/12 - 1/5/13, for Patient #5. Shortened treatment times were noted as follows:</p> <p>12/13/12 3 hours 6 minutes 12/22/12 2 hours 57 minutes 12/27/12 2 hours 50 minutes</p>	V 463		
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V 463	Continued From page 3 This reflected a loss of 97 minutes of dialysis time for Patient #5 during a one month period. No documentation was present to indicate Patient #5 was offered the opportunity to reschedule treatment to make up this loss of dialysis time. In an interview on 1/10/13 from 10:30 AM - 3:00 PM, the nurse manager confirmed the lost time and failure to offer rescheduled time for Patients #1, #5, and #6. The facility failed to ensure three patients received treatments as ordered.	V 463		
V 516	494.80(b)(1) PA-FREQUENCY-INITIAL-30 DAYS/13 TX An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session. This STANDARD is not met as evidenced by: Based on review of medical records and staff interview, it was determined the facility failed to ensure a comprehensive initial assessment was completed within 30 days or 13 treatments of the initiation of dialysis for 1 of 3 patients (Patient #12) who were admitted to the facility during the last quarter of 2012. Failure to complete an initial assessment had the potential to result in unmet patient needs. Findings include: Patient #12 was a 70 year old female who was admitted to the facility on 11/21/12. She was subsequently hospitalized from 12/1 - 12/13/12	V 516	See attached	2/15/13

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V 516	Continued From page 4 and did not dialyze at the facility. Patient #12 returned to the facility for treatment on 12/15/12. Her dialysis prescription included an order for treatment to occur three times a week. She dialyzed each week on Tuesday, Thursday and Saturday. Her record was reviewed for initial assessment on 1/10/13. As of that date, Patient #12 had received 17 outpatient treatments at the facility. However, an initial assessment could not be found. In an interview on 1/10/13 from 10:30 AM - 3:00 PM, the nurse manager confirmed Patient #12 had not yet had a comprehensive assessment completed by the IDT. She stated it was to be done "this week."	V 516		
V 540	494.90 CFC-PATIENT PLAN OF CARE This CONDITION is not met as evidenced by: Based on record review and staff interview, it was determined the facility failed to ensure patient POCs were revised when the current plan did not result in achieving or sustaining the intended outcome. The effect of this failure resulted in patients being placed at risk of complications due to infection and inadequate dialysis. The findings include: 1. Refer to V550 as it relates to the facility's failure to ensure POCs addressed appropriate	V 540	<i>See attached</i>	<i>2/15/13</i>

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V 540	Continued From page 5 vascular accesses for patients.	V 540		
V 550	494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. This STANDARD is not met as evidenced by: Based on record review and staff interview it was determined the facility failed to ensure POCs included a plan for an appropriate vascular access, attained in a timely manner, for 9 of 9 patients (Patients #6 - #11 and #13 - #15) who had dialyzed using a CVC for longer than 90 days, and whose records were reviewed. Findings include: 1. Patient records were reviewed and documented the following: a. Patient #6 was 75 year old female who was admitted to the facility on 7/19/11. She currently dialyzed using a CVC. The content of the vascular access portion of her medical record was a single note, made by the PA on 4/30/12 stating "current CVC. Will arrange consult with surgeon for evaluation of AVF/AVG." Her current POC, dated 10/24/12, stated "Current access: CVC, Rationale: Has appointment with surgeon 10/30/12. Goal: Not met." b. Patient #7 was a 69 year old female who was	V 550	See attached	2/15/13

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V 550	<p>Continued From page 6</p> <p>admitted to the facility on 1/28/11. She currently dialyzed using a CVC. The content of the vascular access portion of her medical record included the following:</p> <p>10/10/11: AVF placement 2/23/11: AVF released for use by surgeon 3/22/12: AVF marked and released for use by surgeon</p> <p>Patient #7's current POC, dated 3/26/12, stated "Current access: CVC. Rationale: met goal."</p> <p>c. Patient #8 was a 39 year old male who was admitted to the facility on 5/10/12. He currently dialyzed using a CVC. The vascular access portion of his medical record was empty. His current POC, dated 6/20/12, stated "Current access: CVC. Rationale: Patient in work up with brother."</p> <p>d. Patient #9 was a 74 year old female who was admitted to the facility on 11/12/11. She currently dialyzed using a CVC. The content of the vascular access portion of her medical record included the following:</p> <p>1/17/11: AVF placed 6/26/12: Transposition of AVF 7/17/12: AVF released for use by surgeon</p> <p>Patient #9's current POC, dated 1/30/12 stated "Current access: CVC. Goal: Not met. Goal: AVF, patient education."</p> <p>e. Patient #10 was a 70 year old female who was admitted to the facility on 10/15/10. She currently dialyzed using a CVC. The content of the</p>	V 550		

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V 550	<p>Continued From page 7</p> <p>vascular access portion of her medical record contained a single note, dated 5/17/11, documenting the removal of a CVC due to sepsis. Her current POC, dated 2/22/12, stated "Current access: CVC. Rationale: Failed AVF x 2. Goal: Met."</p> <p>f. Patient #11 was a 57 year old female who was admitted to the facility on 7/14/12. She currently dialyzed using a CVC. The vascular access portion of her medical record contained a single note, dated 7/7/12, documenting the placement of a CVC. Her current POC, dated 11/28/12 stated "Current access: CVC. Goal: Met. Start using AVF this week."</p> <p>g. Patient #13 was a 64 year old female who was admitted to the facility on 4/5/12. She currently dialyzed using a CVC. The vascular access portion of her medical record contained a note, dated 5/26/12 documenting her evaluation for AVF placement and a note, dated 7/9/12, documenting the placement of an AVF. Her current POC, dated 7/18/12, stated "Current access: NO ENTRY. Goal: Met. Hope to use AVF in place of catheter soon."</p> <p>h. Patient #14 was a 61 year old female who was admitted to the facility on 5/19/12. The vascular access portion of her medical record was empty. Her current POC, dated 9/27/12, stated "Current access: NO ENTRY. Goal: Not met. Rationale: CVC now. Try AVF again after vacation." An 11/12 update stated "Review in 2 months for AVF retry."</p> <p>i. Patient #15 was a 29 year old female who was admitted to the facility on 10/5/11. She currently</p>	V 550		
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V 550	Continued From page 8 dialyzed using a CVC. The vascular access portion of her medical record documented the following: 3/19/12: "AVF functioning well after recent stent placement. Mild steal. May need DRIL procedure to treat left hand eschemia and salvage fistula." 8/25/12: CVC replacement 12/14/12: CVC replacement Patient #15's current POC, dated 1/30/12, stated "Current access: straight graft. Goal: Met." In an interview on 1/10/13 from 10:30 AM - 3:00 PM, the nurse manager showed the surveyor a computerized vascular tracking program. She said the facility had been using it for patients since approximately April 2012. She further said the program contained only current accesses for Patients #6 - #11 and #13 - #15 and did not contain historical vascular access data. In the same interview the nurse manager showed the survey a green binder titled "Vascular Access Log." This binder contained a vascular access tracking sheet that could be manually completed for each patient. However, the tracking sheet was empty and the nurse manager said the facility was not currently using it, but planned to start. The facility failed to provide appropriate monitoring necessary to ensure patients' POCs include a plan to achieve and sustain appropriate vascular access.	V 550			
V 625	494.110 CFC-QAPI	V 625	See attached	2/15/13	

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V 625	Continued From page 9	V 625		
V 627	<p>This CONDITION is not met as evidenced by: Based on staff interview and review of QAPI meeting minutes, it was determined the facility failed to ensure an effective QAPI program was maintained that recognized and corrected problems affecting patients' health. This failure had the potential to decrease the quality of treatment received by patients. Findings include:</p> <p>Refer to V627 as it relates to the facility's failure to ensure the QAPI program recognized trends and develop corrective action plans, for vascular accesses and CVC infections.</p> <p>494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT</p> <p>The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.</p> <p>This STANDARD is not met as evidenced by: Based on facility records and staff interview, it was determined the facility failed to ensure its QAPI program had analyzed vascular access and infection data, resulting in a lack of actions plans being developed and implemented to address extended CVC use and hospitalization rates for septicemia related to CVC use. Findings include:</p> <p>QAPI meeting minutes for twelve months during 2012 were reviewed. The QAPI report included data collected, and areas for trend analysis and process improvement plan.</p>	V 627	See attached	2/15/13

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V 627	<p>Continued From page 10</p> <p>Data collected and reviewed in the QAPI meetings included an "Infection Report." The number of episodes of septicemia during the month were recorded in this section. No target goal was identified. Four episodes of septicemia were recorded and reviewed during the twelve month period. Trend analysis was recorded as "declining" for the four months when cases of septicemia occurred. A process improvement plan was not identified as being needed in response to declining trends.</p> <p>The facility's 2012 Infection Reporting document and the 2012 Hospitalization Discharge Analysis were reviewed and compared to the QAPI data. These reports noted five CVC related infections occurred during the calendar year. Four of these infections resulted in patient hospitalizations for septicemia. The fifth was not categorized as septicemia but did have documented bacterial growth and resulted in CVC removal.</p> <p>The QAPI minutes also included the number of CVCs currently in use in the facility. A target goal was identified as "no catheters." Data was collected and reviewed by the QAPI committee as follows:</p> <p>January 2012: 17% of patients with CVC access in place February 2012: 18.7% of patients with CVC access in place March 2012: 18% of patients with CVC access in place April 2012: 17% of patients with CVC access in place May 2012: 20% of patients with CVC access in</p>	V 627		
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V 627	<p>Continued From page 11</p> <p>place</p> <p>June 2012: 24% of patients with CVC access in place</p> <p>July 2012: 25% of patients with CVC access in place</p> <p>August 2012: 30.9% of patients with CVC access in place</p> <p>September 2012: 25% of patients with CVC access in place</p> <p>October 2012: 29% of patients with CVC access in place</p> <p>November 2012: 29% of patients with CVC access in place</p> <p>December 2012: 28% of patients with CVC access in place</p> <p>CVC numbers were trended as "improving" in January and November QAPI minutes, trended as "no change" in March, April, September, October, and December QAPI minutes and trended as "declining" in February, May, June, July, and August QAPI minutes.</p> <p>During the twelve months of QAPI meeting minutes reviewed, the data reported and reviewed by the QAPI committee showed a significant lack of attaining the targeted goal. However, there was no documentation that a process improvement plan was needed, developed, or implemented in an effort to meet the facility goal as stated.</p> <p>In an interview on 1/11/13 at 9:00 AM, the nurse manager confirmed the QAPI data collected and said the QAPI minutes, as reviewed, were accurate and no process improvement plans had been developed or implemented.</p>	V 627		
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V 627	Continued From page 12 The facility did not identify problem areas of infection and CVC use and did not develop action plans to remedy negative trends.	V 627		
V 714	494.150(c)(1) MD RESP-DEVELOP, REVIEW & APPROVE P&P The medical director must- (1) Participate in the development, periodic review and approval of a "patient care policies and procedures manual" for the facility; This STANDARD is not met as evidenced by: Based on policy and procedure review and staff interview, it was determined the facility failed to ensure policies and procedures were adequate, accurate and up to date. This failure had the potential to impact all facility patients having a developing AVF by delaying the successful use of the AVF. Findings include: During an interview on 1/9/13 at 1:00 PM, the medical director said the facility had the authority to individualize corporate policies for facility use. During an interview on 1/10/13 from 10:30 AM - 3:00 PM, the nurse manager was asked what protocol was used at the facility when starting the use of a new AVF. She provided a corporate document, undated, titled "New AV-Fistula Cannulation Algorithm." The algorithm stated in part, "If complications occur: Stop utilizing the AVF. If a CVC is present, resume dialysis through the catheter. Notify physician for evaluation and/or referral to interventionalist/surgeon." The algorithm did not give guidelines for the assessment or timing of new AVF cannulation.	V 714	<i>See attached</i>	<i>2/15/13</i>

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V 714	<p>Continued From page 13</p> <p>The algorithm did not define complications. The algorithm did not give instructions on how to proceed if a CVC was not present. It did not give directions on how to proceed if needle infiltration occurred.</p> <p>During the same interview on 1/10/13 from 10:30 AM - 3:00 PM, the Regional Quality Director was present. She provided a more current corporate document, dated 7/4/12, titled "Assessment and Cannulation of a New A-V Fistula." She said this updated procedure should be used and was available in the corporate computerized P&P.</p> <p>Upon review it was noted the updated procedure addressed assessment for the first use of new AVFs and provided an algorithm that included a progression plan for larger needles and increased BFR, interventions for complication, and infiltration guidance.</p> <p>In the same interview on 1/10/12 from 10:30 AM - 3:00 PM, the nurse manager said she was not aware a new algorithm was available.</p> <p>The facility did not provide adequate direction to staff for timely, successful utilization of new vascular accesses.</p>	V 714		
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