



IDAHO DEPARTMENT OF
HEALTH & WELFARE

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BUREAU OF FACILITY STANDARDS
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CERTIFIED MAIL: 7000 0520 0023 1950 8503

November 13, 2006

FILE COPY

Shirley Rudebaugh
North Idaho Dialysis Facility
2100 Ironwood Court
Coeur D'Alene, ID 83814

Dear Ms. Rudebaugh:

Based on the survey completed at North Idaho Dialysis Facility on November 1, 2006 by our staff, we have determined that North Idaho Dialysis Facility is out of compliance with the Medicare ESRD Conditions of Participation on Governing Body and Management (42 CFR 405.2136). To participate as a provider of services in the Medicare Program, a ESRD must meet all of the Conditions of Participation 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 Facility 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 of Participation referenced above by submitting a written Credible Allegation of Compliance. Such corrections must be achieved and compliance verified, by this office, before **December 15, 2006**. **To allow time for a revisit to verify corrections prior to that date, your Credible Allegation must be received in this office no later than December 7, 2006.**

The following is an explanation of a credible allegation:

Credible allegation of compliance. A credible allegation is a statement or documentation:

- Made by a provider/supplier with a history of having maintained a commitment to compliance and taking corrective actions if required.
- That is realistic in terms of the possibility of the corrective actions being accomplished between the exit conference and the date of the allegation, and
- That indicates resolution of the problems.

In order to resolve the deficiencies the facility must submit a letter of credible allegation to the Department, which contains a sufficient amount of information to indicate that a revisit to the facility will find the problem corrected.

As mentioned above, the letter of credible allegation must indicate that the problems have been corrected as of the date the letter is signed. Hence, a plan of correction indicating that the correction(s) will be made in the future would not be acceptable. Please keep in mind that once the Department receives the letter of credible allegation, an unannounced visit could be made at the facility at any time.

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,



SYLVIA CRESWELL
Supervisor
Non-Long Term Care

SC/mlw

Enclosures

Sylvia Creswell
Supervisor Non-Long Term Care
Idaho Department of Health & Welfare
Bureau of Facility Standards
3232 Elder Street
P.O. Box 83720
Boise, Idaho 83720

December 6, 2006

Dear Ms. Creswell:

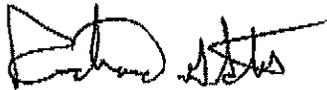
The purpose of this letter is to respond to the Idaho Department of Health & Welfare Statement of Deficiencies regarding serious violations cited at the North Idaho Dialysis facility during the November 1, 2006 survey. This letter with attached form CMS-2567 provides credible allegation that those deficiencies cited as a result of the referenced re-licensing survey have been corrected and that the facility is now in full compliance with the Bureau of Facility Standards applicable regulations. As such, we request that the Bureau revisit the facility to substantiate compliance.

The corporate and field management of Fresenius Medical Care North America (FMCNA) and the Governing Body of the North Idaho facility take serious their responsibility to develop, implement, and manage policies and procedures that ensure the health and safety of the facility's patients.

The attached form, CMS-2567 documents all corrective actions which have taken place. Based on the corrective actions, education and added routine daily monitoring as well as systemic CQI and Governing Body review, we believe that the facility is currently operating in compliance with applicable federal and state regulation and welcome the opportunity to demonstrate such compliance at a revisit.

We appreciate your review of this plan, the opportunity to meet with you and your consideration of the current status of the facility in light of the plan.

Sincerely,



Richard G. Stotz
Area Manager

CENTERS FOR MEDICARE & MEDICAID SERVICES				11/09/2005 FORM APPROVED OMB NO. 0938-0391
NAME OF PROVIDER OR SUPPLIER		PROVIDER ID NUMBER	STREET ADDRESS, CITY, STATE, ZIP CODE	(X3) DATE SURVEY
North Idaho Dialysis Unit		133500	2005 Lincoln Way Coeur D'Alene, ID 83814	11/01/2006
(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
V000	<p>INITIAL COMMENTS</p> <p>The following deficiencies were cited during the Medicare recertification survey of your ESRD facility. The surveyor conducting the recertification visit was Gary Guiles, RN, HFS. Acronyms used in this report include:</p> <p>ml=milliliter RN=Registered Nurse</p>			
V 110	<p>405.2136 GOVERNING BODY AND MANAGEMENT</p> <p>The ESRD facility is under the control of an identifiable governing body, or designated person(s) so function, with full legal authority and responsibility for the governance and operation of the facility.</p> <p>This CONDITION is not met as evidenced by:</p> <p>Based on review of clinical records, facility policies and occurrence reports, and staff interview, it was determined the governing body failed to assume responsibility for the governance and operation of the facility. The governing body failed to assume responsibility for maintaining and implementing written personnel procedures that ensured reports of incidents and accidents were documented and reviewed to identify health and safety hazards (V146). The cumulative effect of the systemic practice resulted in the facility's inability to ensure safe dialysis</p>	V110	<p>GOVERNING BODY AND MANAGEMENT</p> <p>The corporate and field management of Fresenius Medical Care North America (FMCNA) and the Governing Body of the North Idaho facility take serious their responsibility to develop, implement, and manage policies and procedures that ensure the health and safety of the facility's patients through ensuring a system of reporting incident and accidents to provide documentation and subsequent review to identify health and safety hazards and develop systems for the prevention of similar incidents in the future.</p> <p>The following is a detailed description of activities undertaken to correct and prevent a recurrence of the noted deficiencies.</p> <p>On November 1st, immediately post the exit interview Rick Stotz Area Manager, Shirley Rudebaugh Clinical Manager, Jean Stevens RVP, Karen Larson Regional Quality Manager (RQM) and Sue Lewis, Regional Educator met in</p>	12/06/2006

	<p>services would be provided.</p>		<p>person/conference call to develop a plan of action/correction.</p> <p>In addition, the Governing Body met on Wednesday, November 22nd, 2006 to review the Statement of Deficiencies and Plan of Correction as developed above. The Governing Body agreed to meet each month to monitor the progress of the Plan of Correction by hearing reports from persons designated as being responsible for respective actions. The Governing Body developed a schedule for the monthly meetings. The minutes of the above referenced Governing Body meeting and subsequent meetings will document their occurrence and are available in the facility for review.</p> <p>Furthermore, the Governing Body met again on December 6, 2006 to further review, amend and approve the final actions as being undertaken in the Plan of Correction.</p> <p>A process to report/document and review health and safety hazards has been developed as noted below in V 146</p>
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<p>V146</p>	<p>405.2136(d)(2)PERSONNEL P/P:INCIDENTS REVIEWED</p> <p>The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedurcs that ensure that reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards.</p> <p>This STANDARD is not met as evidenced by:</p> <p>Based on review of facility administrative records and clinical records and staff interview, it was determined the facility's governing body failed to implement written personnel policies and procedures regarding incidents. The facility failed to investigate incidents involving medication errors for 3 of 3 patients (#s 7, 9, and 10) in order to identify health and safety hazards. The findings include:</p> <ol style="list-style-type: none"> 1. Incident reports for 2006 revealed 3 similar medication errors involving 3 separate patients (#s 7, 9, and 10). These included: <p>Patient #9 was a 55 year old Hemodialysis patient who received the incorrect does of Heparin during her run on 2/23/06. The patient was supposed to receive 0.5ml of Heparin per hour (1000 units per ml). Instead, the Heparin pump was set to deliver 5 ml per hour. The patient received 4900 units of Heparin more than was ordered before the error was discovered. No unusual bleeding was documented in the record.</p> <p>Patient #10 was a 60 year old Hemodialysis patient who received the incorrect dose of Heparin during her run on 4/3/06. The patient was</p>	<p>V146</p>	<p>PERSONNEL P/P:INCIDENTS REVIEWED</p> <p>The following is a briefly stated and bulleted list of corrective actions that have been implemented:</p> <ul style="list-style-type: none"> • On November 8th, 2006 the Clinical Manager did a complete review of the previous three incidents to determine the root cause and subsequently determine if the policy changes implemented in August as noted below - are sufficient to prevent further recurrence of this incident. Note the incidents as noted in the Statement of Deficiency occurred in February, April and June 2006, before the implementation of the new policies. It was determined that the root cause was that one technician had made the same error in all three incidences. With the below noted policies in place, there have been no further heparin dosing errors made by this technician. The Clinical Manager spoke with the technician regarding these incidents and a copy of the policics was given to the tech as further reinforcement. Further, the Clinical Manager reviewed the findings with the Medical Director who concurred with the actions. <p>Although the root cause was felt to be specifically related to one staff member, the Governing Body required the entire clinical staff to be retrained. Therefore, the Regional Quality Manager contacted the VP Education/Regional Director of Education to develop staff re-training based upon the citations in the Statement of Deficiencies and as of November 27th, 2006, the following education has been completed.</p>	<p>12/06/2006</p>
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<p>supposed to receive 0.5 ml of Heparin per hour. Instead, the Heparin pump was set to deliver 5 ml per hour. The patient received 5750 units of heparin more than was ordered before the error was discovered. No unusual bleeding was documented in the record.</p>	<p>Patient #7 was a 64 year old Hemodialysis patient who received the incorrect dose of Heparin during his run on 6/17/06. The patient was supposed to receive 0.5 ml per hour. The patient received 2900 units of Heparin more than was ordered before the error was discovered. No unusual bleeding was documented in the record.</p>	<ul style="list-style-type: none"> • Policy 9 HT – 1.01 “Pre-treatment Safety Checks” Policy 9 HT – 1.04 “Monitoring the Patient During Hemodialysis.” • Policy 20 RM –1.01 “Confidential Patient Occurrence Reporting.” • By November 27th, 2006 all patient care personnel at this facility were re-trained to perform all pre-treatment safety checks as noted per policy
<p>2. The policy “Confidential Patient Occurrence Reporting”, revised 5/22/05, stated a Confidential Patient Occurrence Report was to be completed and “submitted to the Quality Improvement Committee Coordinator within 24 hours of the Patient Occurrence”. The committee was supposed to review the report “for pattern of care and practice standard trends.” This was not done. Quality Management meeting minutes for 2006 were reviewed. No mention of the medication errors was included in the minutes.</p>	<p>The Clinical Manager was interviewed on 10/31/06 at 10:35 AM. She stated she had talked to staff following the medication errors. She said the incidents had not been investigated in order to determine the cause of the incidents and whether or not the facility’s procedures needed to be changed to prevent continued errors. She said no action had been taken to prevent these types of errors beyond counseling staff.</p>	<p>The Clinical Manager, on November 27, 2006, conducted a mandatory staff meeting for all patient care staff to reinforce management expectation and staff responsibility to adhere to facility adopted policy and procedures. The Clinical Manager discussed and reinforced ramifications of non-compliance on the part of the staff that are found not to comply with FMS Policy and Procedures.</p>
		<p>Effective November 27, 2006, and ongoing, the Charge Nurse or their appointed designee is responsible to monitor the patient treatment sheets after each patient’s dialysis treatment for compliance to policy on pre-treatment safety checks and the direct reporting of any identified non-compliance to the Clinical Manager who will address with reeducation and/or progressive disciplinary action.</p>
		<p>In addition, the RQM met with the Clinical Manager on November 7th, 2006 to provide education and the Quality Improvement Analysis tool which is used to determine the root cause of patient occurrences. The Analysis tool was implemented on November 7th, 2006, and will be instrumental in ensuring the tracking/trending of all incident reports as they occur. The tool was used November 8, 2006 for the root cause analysis of the</p>

			<p>three mentioned incident reports in the Statement of Deficiency.</p> <p>Additionally, effective November 8, 2006, the Quality Analysis Tool will be used by the Clinical Manager on every patient incident report that is received. These will be monitored at the CQI meeting.</p> <p>Ongoing the Clinical Manager will audit incident reports as part of the Facility Quality Management Program and findings will be reflected in the monthly CQI meeting minutes.</p> <p>The Clinical Manager is responsible for overseeing performance of all facility personnel, and for providing feedback related to performance. The Clinical Manager will communicate to the Area Manager identified non-compliance as well as when educational needs are identified.</p> <p>The Clinical Manager is responsible for presenting all auditing/monitoring data to the CQI committee for oversight. This is documented in the CQI Minutes. The Area Manager is responsible to present the progress/status of the Plan of Correction monthly to the Governing Body who is ultimately responsible.</p> <p>Minutes of both CQI and Governing Body meetings will be available for review at the facility.</p>	
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<p>V193</p>	<p>405.2137(b)(1) PATIENT CARE PLAN: INDIVIDUALIZED</p>	<p>V193</p>	<p>PATIENT CARE PLAN: INDIVIDUALIZED</p>	<p>12/06/2006</p>
<p>The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short term goals.</p>		<p>The Governing Body will ensure that the patient care plan is personalized for each patient reflecting their individual needs as well as any modification necessary to achieve their long and short term goals.</p>		
<p>This STANDARD is not met as evidenced by:</p>		<p>The Area Manager, Clinical Manager, VP Education/Regional Director of Education and Regional Quality Manager met/conference called on November 1, 2006 to review the requirements for patient care plans as defined in 405.2137 and Policy/Procedure # 17 PP-1.02 to ensure that all care plans are individualized for each patient.</p>		
<p>Based on review of clinical records and facility policies and observation and staff interview, it was determined the facility failed to ensure patient care plans were personalized and reflected individual psychological, social, and functional needs of 3 of 11 patients (#s 1, 2, and 11) whose records were reviewed. The findings include:</p>		<p>In addition, on November 21, 2006 the Computerized Medical Record processes were reviewed by the Regional Quality Manager, Regional Director of Education, and Clinical Manager to determine the best way to utilize the current electronic charting system to ensure additional individually personalized patient care planning notes and documentation are present, tracked and retrievable.</p>		
<p>1. Three sampled patients had unique problems that had not been addressed in a plan of care. Theses include:</p>		<p>Effective November 27, 2006, nurses, social worker, and dietician will document/classify any of their notes that pertain to a change in status for the patient, or as individual needs arise as a care plan progress note. These care plan notes will be reviewed at the multi disciplinary care conference to include physician input and will be added to the patient's plan of care to reflect the patient's individual needs.</p>		
<p>Patient #1 was a 77 year old male who began Hemodialysis on 5/11/06. He lived in a local skilled nursing facility. He had a fractured hip which was surgically repaired in July 2006. He dialyzed in his wheel chair and not in a dialysis chair. He dialyzed for over 4 hours 3 times per week. He was observed dialyzing at 12:30 PM on 10/30/06. His lower legs and feet were almost black due to poor circulation. He did not have any sores on his feet which staff checked at the time. He groaned in pain when he was moved. The RN on duty stated he had dialyzed in his wheel chair since</p>		<p>The VP Education/Regional Director of Education and Regional Quality Manager developed staff re-training based upon the citations in the Statement of Deficiencies and as of November 27, 2006, the following education has been completed including but not limited to the following:</p>		

his fractured hip due to pain in transferring.

Patient #1's "HEMODIALYSIS SHORT TERM CARE PLAN", dated 8/16/06, did not address positioning for comfort and pain control during dialysis.

Patient #2 was a 65 year old female who began hemodialysis on 7/15/00. She lived in a local skilled nursing facility. She had a history of stroke and was confined to a wheel chair. She was obese, weighing 220 pounds. She was not able to assist with transfers and repositioning. She was observed dialyzing in her wheel chair at 12:30 PM on 10/30/06. She did not dialyze in a dialysis chair. She had a pressure sore on her right foot with a clean dry dressing. She dialyzed for over 4 hours 3 times per week. The Clinical Manager was interviewed on 11/1/06 at 8:10 AM. She stated a physical therapist had provided an inservice to facility staff in August 2006 regarding positioning this patient. She said since the inservice, a staff member had been injured while moving the patient.

Patient #2's "HEMODIALYSIS SHORT TERM CARE PLAN", dated 8/16/06, did not address positioning for comfort and the prevention of skin breakdown during dialysis.

Patient #11 was a 69 year old female who began Hemodialysis on 1/9/06. She lived in a rural town approximately 60 miles from the facility. She consistently missed dialysis treatments. A printout documented 31 missed dialysis treatments between June 1 and

- 17 PP 1.02 "Hemodialysis Short Term Care Plan."
- Instruction on documenting progress notes as a plan of care

In addition, as of December 4th, 2006, 100% of care plans were audited by the clinical manager to insure that each plan of care was individualized to the patient's needs.

Additionally, 25% of the care plans will be audited each quarter, in January, April, July and October to ensure they are all individualized and that all will be audited throughout the year. The results will be tracked in the Facility Quality Management Binder.

The Clinical Manager is responsible for presenting all auditing/monitoring data to the CQI committee for oversight. This is documented in the CQI Minutes. The Area Manager is responsible to present the progress/status of the Plan of Correction monthly to the Governing Body who is ultimately responsible.

October 31, 2006. The Clinical Manager was interviewed on 11/1/06 at 9 AM. She stated staff had attempted to work with this patient but had not been able to decrease her non-compliance. The most recent social service note, dated 8/3/06, had checked "Stable transportation status" and "Has reported some car problems as reasons for missing treatments". No social service plan was documented to address the missed visits.

Patient #11's "HEMODIALYSIS SHORT TERM CARE PLAN", dated 2/8/06, did not address the compliance issues. The Clinical Manager, interviewed on 11/1/06 at 9 AM, stated a more recent care plan had been developed but it had been misplaced and was not available.

2. The facility utilized a standardized short term care plan for all patients. It was generated in part by a computer. It covered areas common to dialysis patients such as adequacy, bone disease, anemia, access, etc. For most patients this was sufficient. The plan did not lend itself to unique problems such as the positioning issues for Patients #s 1 and 2. None of the 11 plans of care reviewed addressed problems outside of the common dialysis issues. Also the policy "Hemodialysis Short-term Care Plan", revised 12/20/05, did not address planning for problems unique to individual patients.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

[Handwritten Signature]

TITLE

[Handwritten Title]

(X6)DATE

[Handwritten Date]

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that 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.