IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
RUSSELL S. BARRON– Director

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June 19, 2018

Joni Kelley, Administrator
Lewis-Clark Kidney Center
2116 12th Avenue
Lewiston, ID 83501

RE: Lewis-Clark Kidney Center, Provider #132530

Dear Ms. Kelley:

Based on the survey completed at Lewis-Clark Kidney Center, on June 1, 2018, by our staff, we have determined Lewis-Clark Kidney Center is out of compliance with the Medicare ESRD Conditions for Coverage of **Compliance with Fed/State/Local Laws (42 CFR 494.20) and 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 these conditions to be unmet, substantially limit the capacity of Lewis-Clark 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;
- 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 July 16, 2018. 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 July 2, 2018.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **July 2, 2018**.

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.

Thank you for the courtesies extended to us during the survey. If you have any questions, comments or concerns, please contact Dennis Kelly, RN or Nicole Wisenor, Co-Supervisors, Non-Long Term Care at (208) 334-6626, option 4.

Sincerely,

NICOLE WISENOR, Supervisor
Non-Long Term Care

NW/pmt
Enclosures
ec: Debra Ransom, R.N., R.H.I.T., Bureau Chief
Patrick Thrift, Survey & Certification Manager Region X
Julius Bunch, Certification & Enforcement Manager Region X

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	132530	A. BUILDING _____ B. WING _____	C 06/01/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LEWIS-CLARK KIDNEY CENTER	2116 12TH AVENUE LEWISTON, ID 83501

(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 The following deficiencies were cited during the complaint survey at your facility from 5/29/18 - 6/1/18. The surveyor conducting the survey was: Trish O'Hara, RN Acronyms used in this report include: AA - Administrative Assistant AVF - ArteioVenous Fistula BFR - Blood Flow Rate FA - Forearm HT - Home Therapies L - Liter Lt - Left MSW- Master of Social Work PCT - Patient Care Technician QAPI - Quality Assessment Performance Improvement RD - Registered Dietician RN - Registered Nurse SNF - Skilled Nursing Facility TQM - Total Quality Management The facility was notified of an immediate jeopardy at V 101 on 5/31/18 at 1:30 PM. A plan of correction was submitted and accepted on 5/31/18 at 4:30 PM. Verification of the plan's implementation was completed on 6/1/18 at 11:00 AM., and the immediate jeopardy was removed.	V 000	**V 000** The governing body and management staff of this facility take this deficiency statement very seriously and will work to bring the cited deficiencies into compliance and will ensure that they remain in compliance. The governing body met on 6/26/2018 to review and approve the Plan of Correction (POC) and the tools that will keep the approved plan in compliance. All attachments and in-services are also available at the facility for review. The governing body will meet monthly for the next six months to review the Plan of Correction and ensure that the citations are remaining in compliance. The findings from these reviews will also be discussed at monthly Total Quality Management (TQM) meetings.	6/26/18
V 100	CFC-COMPLIANCE WITH FED/STATE/LOCAL LAWS CFR(s): 494.20	V 100	**V100 494.20 CFC – Compliance with Fed/State/Local Laws** ***Cross reference V 101*** In-services were initiated on emergency situations and the Idaho Administrative Code with all direct patient care staff on 6/1/18 and all staff were in-serviced prior to performing direct patient care as indicated in the statement of deficiencies. Staff was re in-serviced on	6/27/18

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

CM 6/27/18

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 100	Continued From page 1 This CONDITION is not met as evidenced by: Based on record review, policy review, and staff interview it was determined the facility failed to ensure staff compliance with applicable Idaho State Board of Nursing Rules. This impacted the health and safety of 1 of 4 patients (Patient #1) whose records were reviewed, and had the potential to impact all patients receiving services at the facility. This failure resulted in patients being placed at risk of serious harm, impairment or death due to a lack of adequate treatment. The findings include: Refer to V 101 as it relates to the failure of RNs to respond appropriately to a patient emergency.	V 100	emergency situations and the Idaho Administrative code as indicated in the cross referenced V-tag. The Clinic Manager will spot check all treatment sheets once a week for a minimum of 12 weeks to ensure staff are following the new facility procedure for Emergency Complications and that nurses are following up and documenting all dialysis complications and indicated in the referenced v-tag. A clinic manager monitoring tool was developed to track this monitoring. The findings from the CM monitoring tool will be reviewed at the monthly Total Quality Management meetings and the monthly governing body meetings (for six months), where additional	
V 101	COMPLIANCE WITH FED/STATE/LOCAL LAWS CFR(s): 494.20 The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements. This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, it was determined the facility failed to ensure staff responded appropriately during an emergency situation for 1 of 4 patients (Patient #1) whose records were reviewed. This failure placed all patients dialyzing at the facility at risk of an emergent physical condition not being immediately addressed. Findings include: 1. The Rules of the Idaho Board of Nursing, IDAPA 23.01.01.401.01.fii, defined the responsibilities of the Registered Nurse to include	V 101	action will be taken as deemed appropriate such as additional training, continuing the clinic manager monitoring or if trends are identified, disciplinary action. **V 101** Re in-service to all Direct Patient Care (DPC) staff was initiated on 6/27/2018 by the clinic manager regarding emergency situations and review of the Idaho Administrative Code. **(See attached in-service record).** Procedure 5-01 (Emergency Complications – Hospital Referral Criteria) was developed which states: *"The patient must be referred to the hospital emergency room for physical evaluation by a physician for the following (pre, intra, post dialysis):* • *Altered level of consciousness* • *Unresolved Tachycardia (Heart rate over 120)*	6/27/2018

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V 101	Continued From page 2 "Evaluating patient status and instituting appropriate therapy or procedures which might be required in emergency situations to stabilize the patient's condition or prevent serious complications..." Additionally, a facility policy titled "Emergency Care Policy," dated 10/09/2000, stated "In an emergency situation, 911 is called immediately." Patient #1 was a 69 year old female who resided at a SNF. She had a comorbid diagnosis of Atrial Fibrillation (a fast, irregular heart rate) and was being treated for this condition with Eliquis (an anticoagulant medication). Prior to her dialysis treatment on 5/11/18, the facility was notified by the SNF that Patient #1 had fallen and hit her head. The facility accepted her for treatment, but withheld her ordered intradialytic Heparin (an anticoagulant medication). Patient #1's 5/11/18 treatment record showed she had experienced tachycardia (a heart rate greater than 100 beats/minute) consistently during her 4 hour treatment from 6:14 AM - 10:16 AM. The PCT documented the RN was notified of Patient #1's elevated heart rate at 7:46 AM, and again at 9:30 AM. No documentation was present showing the RN responded to the notifications. A post treatment nursing note stated Patient #1 was confused and did not know where she was or what year it was. She was unable to stand and her heart rate was 134 beats/minute. She had a blank stare on her face, and her oxygen saturation was at 80%. Oxygen was increased from 2 L/min to 4 L/min. The physician was	V 101	• *Unresolved Bradycardia (Heart rate less than 40)* • *Unresolved Hypertension (SBP >200 and DPB >110)* • *Unresolved Hypotension (SBP <90 and patient is symptomatic and <70 and patient is asymptomatic)* • *Unresolved Nausea and Vomiting* • *Unresolved access bleeding post dialysis treatment* • *Unresolved dizziness* • *Unresolved chest poin* • *Unresolved Hyperglycemia* • *Unresolved Hypoglycemia* • *Anaphylaxis reactian* • *Air Embolus* • *Hemolysis* • *Blood Loss* • *Seizures"* The procedure also states: *"If the physician is contacted and does not give an order far transfer and based on the nursing assessment, the nurse feels the patient needs to be evaluated, the nurse can make an independent decision, to transfer the patient for evaluation with support from the medical director and without feor of reprisol."* **(See attached Procedure 5-01)** During the in-service it was stressed that anytime a patient meets the above criteria, the patient must be sent to the emergency department for evaluation. During the in-service the Idaho administrative code was reviewed which includes the responsibility of the registered	

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V 101	Continued From page 3 notified and gave orders to administer Metoprolol 25 mg (a medication to decrease heart rate) and to discharge Patient #1 to her SNF. The post treatment nursing note also stated the SNF was notified about Patient #1's condition and was told she "would need assessment as soon as she arrived back to them." She was discharged to the SNF at 10:57 AM. Subsequently, Patient #1 was hospitalized from 5/11/18 - 5/17/18 for treatment of Atrial Fibrillation with rapid ventricular response, urinary tract infection, hypertension, altered mental status, and low serum sodium. In an interview on 5/30/18 at 4:00 PM, RN A said he considered calling 911 for Patient #1 and thought he may have even mentioned it to the physician on the telephone, but the physician wanted Patient #1 to return to her SNF. In an interview on 5/30/18 at 2:30 PM, RN B said she did not have an order to call 911, but did have a physician's order to return Patient #1 to her SNF. In an interview on 5/31/18 at 1:00 PM, the Clinic Manager stated she was on site but was not made aware of Patient #1's condition. The facility failed to ensure the RNs, in accordance with Idaho Board of Nursing Rule IDAPA 23.01.01.401.01.f and the facility policy, responded appropriately to an emergent patient situation. This failure placed Patient #1 at risk of serious harm, impairment, or death due to a lack of adequate treatment.	V 101	nurse as: *"Evaluating patient status and instituting appropriate therapy or procedures which might be required in emergency situations to stabilize the patient's condition or prevent serious complications in accordance with standard procedures established by the policy-making body in the health care setting, including but not limited to administration of intravenous drugs and starting intravenous therapy based on protocols if the patient has been assessed and determined to be in peril"* Emphasis was placed on the responsibility of the nurse to ensure the patient receives appropriate medical evaluation by a physician without the fear of reprisal. It was also stressed that anytime a patient has a dialysis complication such as tachycardia and decreased oxygen saturation, the nurse must perform an assessment of the patient and document their findings, which includes any medical interventions, including medication administration and follow up to the interventions. The clinic manager (CM) will spot check all treatment sheets once a week for a minimum of 12 weeks that all patients are sent to the emergency department as indicated in the new procedure and that all dialysis complications, including tachycardia and decreased oxygen saturations are evaluated by the registered nurse with interventions (and follow up) and that all is documented in the patient's medical record. **(See attached CM monitoring tool)** The Clinic Manager will ensure compliance through completion of the CM monitoring tool and all findings will be addressed at the monthly Total Quality	

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V 101	Continued From page 4 The facility was notified of the immediate jeopardy on 5/31/18 at 1:30 PM. A plan of correction was submitted and accepted on 5/31/18 at 4:30 PM. The plan stated, before administering patient care, all direct care staff will be inserviced on the following: - Revised Procedure 5-01, Emergency Complications - Hospital Referral Criteria. This revision included 16 criteria for patient transfer to the emergency department for physical evaluation by a physician. - Review of Idaho Administrative Code IDAPA 23.01.01.401.fii which includes the responsibility of the registered nurse to evaluate patient status and institute appropriate therapy or procedures which might be required in emergency situations. - A new policy stating the RN can make an independent decision, based on nursing assessment, to transfer a patient to the hospital for evaluation, with support from the medical director and without fear of reprisal. Verification of the plan's implementation, by observation and interview, was completed on 6/1/18 at 11:00 AM, and the immediate jeopardy was removed.	V 101	Management (TQM) meeting where additional action will be taken as deemed appropriate by the committee, such as further education, continuing the CM monitoring and/or disciplinary action.	
V 625	CFC-QAPI CFR(s): 494.110 This CONDITION is not met as evidenced by: Based on staff interview, and review of Incident Reports, treatment records, and QAPI meeting minutes,it was determined the facility failed to	V 625	**V 625 494.110 CFC – QAPI** ***Cross Reference V 626; V634*** In-services were initiated with the Direct Patient Care (DPC) staff and the Total Quality Management (TQM) Committee on 6/27/2018 to review the cited issues as listed in the referenced V-tags. The in-services included review of policies for Incident Reporting and the requirements for the trending and tracking in TQM allowing the TQM committee to identify root cause analysis and to develop action plans to reduce further incidents. Also included in the in-service was the review of the reportable incidents as outlined in the TQM Risk Management policy. The Clinic Manager will document all incidents starting from January 2018 to present on the Incident Summary Report and bring this report (along with the Incident Reports) to the TQM meeting for review. The committee will note any trends, determine root cause analysis, and develop action plans to prevent further incidents. The Clinic Manager will notify the Corporate Clinical Regulatory Manager (CRM) of all incidents in the facility. The CRM in conjunction with the CM will review each incident report for a minimum of 3 months (then continue required monthly monitoring) to ensure the CM demonstrates	6/27/2018

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V 625	Continued From page 5 ensure an effective QAPI program was developed and maintained to recognize and minimize problems affecting patients' health. This failure directly impacted 10 of 12 ICHD patients (Patients #1 - #10) and resulted in the facility's inability to evaluate the quality of patient care. Findings include: 1. Refer to V 626 as it relates to the facility's failure to develop and implement an effective QAPI program. 2. Refer to V 634 as it relates to the facility's failure to collect and assess complete, accurate data related to adverse events.	V 625	understanding of comprehensive documentation of the incident identifying the root cause analysis and the action taken to prevent incidents from reoccurring. All incident reports must be reviewed at the monthly TQM meeting. A CRM monitoring was developed to track this monitoring. In addition, an incident report was completed on Patient #1 on 6/27/2018 and a Clinic Manager Audit tool was developed to track monitoring of the treatment sheets for a minimum of 12 weeks to identify any reportable events as listed in the TQM Risk Management policy. The findings from the CM monitoring tool and the CRM monitoring tool will be reviewed at the monthly	
V 626	QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL CFR(s): 494.110 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	V 626	Total Quality Management meetings and the monthly governing body meetings (for six months), where additional action will be taken as deemed appropriate such as additional training, continuing the clinic manager monitoring or if trends are identified, disciplinary action. **V626** The Corporate Clinical Regulatory Manager (CRM) initiated an in-service with the Total Quality Management (TQM) Committee on 6/27/2018 to review the process of Incident Reporting and tracking by the TQM committee **(see attached in-service record)**. During the in-service it was stressed that the incident report should be a comprehensive report including cause of the incident and methods used to prevent the incident from happening again. The policy was reviewed which states *"Incident Reports will be reviewed and trended. These reports must be complete*	6/27/2018

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V 626	Continued From page 6 meeting minutes, policy, and Incident Reports, it was determined the facility failed to ensure an effective, data-driven quality assessment and performance improvement program was implemented and maintained. This failure directly impacted 10 of 12 patients (Patients #1 - #10) whose treatment records and Incident Reports were reviewed, and had the potential to impact all patients receiving care at the facility. This prevented the facility from analyzing outcomes and limited the facility's ability to correct deficiencies in patient care. Findings include: The QAPI or TQM (Total Quality Management) committee included the Medical Director, Clinic Manager, MSW, RD, AA, and HT RN. Data presented to the TQM committee included Incident Reports. Incident Reports were generated based on a list of events included in the "Total Quality Management" policy, revised 3/15/16. The Incident Report included sections titled "Narrative of incident, including treatment and resolution," "Comments of Clinical Manager," "Comments of Medical Director," "Action taken to prevent incident from reoccurring," and "Additional Comments". Ten Incident Reports from 4/25/18 - 5/25/18 were reviewed. Incident Reports did not comprehensively include cause or prevention. Examples included, but were not limited to, the following: - On 4/27/18 an Incident Report was completed for a medication error involving Patient #10. The Narrative section stated "Pt. had his dialysis	V 626	*and signed by the Medical Director. Events that repeat will be trended and action plans formulated to reduce or eliminate the problem. e.g. medication errors, accidents, adverse drug reactions, etc. that could affect patients, staff and visitors."* A detailed review of completing the incident report was given, with emphasis placed on how to complete the section "Action Taken to Prevent Incident from Reoccurring" **(see attached form)**. It was also stressed that the Clinic Manager is responsible for completing the Incident Report form and documenting the incident in the TQM minutes. The Incident Report form, along with the Incident Summary Report **(see attached form)**, must be taken to the TQM meeting for further review and discussion by the TQM committee where trends should be identified, root cause analysis documented and the action taken to prevent the incident from reoccurring. The policy states *"All incidents are to be reported to the Clinic Manager/DON and require his/her signature on the form. The Medical Director must also be notified of all events and comments and signature are required on the form. All incident reports will be faxed to the Manoger of Clinical and Regulatory Services from the facility for review. All Incidents are to be discussed at the Total Quality Management meeting. During this meeting, plans need to be formulated for those incidents that could be prevented or reduced. Reoccurring incidents need to be tracked and trended and discussed at each TQM Meeting until a satisfactory outcome is obtained."* The Clinic Manager will document all incidents starting from January 2018 to present on the Incident Summary Report and bring this report (along with the Incident Reports) to the next TQM meeting for review by the TQM committee. The committee will note any trends, determine root cause analysis,	

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V 626	Continued From page 7 treatment heparin held today because of concern involving the dehiscence of recently created Lt. FA AVF. The attending PCT thought that meant to hold the Heparin Locks as well. Pt. only received the NS lock to each Hemocath limb." Clinic Manager Comments stated "Communication needs improved between the Nurses and the Techs." The Action Taken to Prevent Incident from Reoccurring section stated "Charge RN should properly communicate to the techs and monitoring medications appropriately." No root cause analysis was documented determining the actual cause of the medication error. No preventive action plan was documented. - On 5/21/18 an Incident Report was completed for a missed lab error involving Patient #4. The Narrative section recounted empty blood tubes being found on the floor. Scheduled patient lab tests were not drawn and had to be rescheduled. Clinic Manager Comments stated "I'm seeing a pattern from one specific PCT not following through on patient orders and or making mistakes by not paying attention." The Action Taken to Prevent Incident from Reoccurring section stated "Staff need to slow down during patient pre treatment to follow through each step and follow policies and procedures." No root cause analysis was documented determining the actual cause of the missed lab error. No preventive action plan was documented. - On 5/18/18 an Incident Report was completed for a treatment error involving Patient #5. The Narrative section stated "Pt taken off for	V 626	and develop action plans to prevent further incidents. The Clinic Manager will notify the Corporate Clinical Regulatory Manager (CRM) of all incidents in the facility. The CRM in conjunction with the CM will review each incident report for a minimum of 3 months (then continue required monthly monitoring) to ensure the CM demonstrates understanding of comprehensive documentation of the incident identifying the root cause analysis and the action taken to prevent incidents from reoccurring. All incident reports must be reviewed at the monthly TQM meeting **(See attached CRM monitoring tool)**. The Clinic Manager will ensure Compliance through reviewing all incident reports in the monthly TQM meeting where further action will be taken as deemed appropriate by the committee.	

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V 626	Continued From page 8 bathroom at 1236, returned at 1245...BFR not increased to prescribed rate ran rest of treatment at 200 BFR." Clinic Manager Comments stated "This shows me how techs are not thoroughly going through the process of looking at everything during their checks and during each vital sign checks or this wouldn't have been forgotten while the patient was placed back on treatment." The Action Taken to Prevent Incident from Reoccurring section stated "At our last Thursday Mandatory staff meeting, I had inserviced all staff on Safety checks pre and during treatments. All staff had signed and will be held accountable." No root cause analysis was documented determining the actual cause of the treatment error. No preventive action plan was documented. In an interview on 5/31/18 at 1:00 PM, the Clinic Manager explained the incident report process. After receiving the report, she completed the Clinic Manager comments and the Action Taken to Prevent Incident from Reoccurring section. She said she did not talk to staff to determine possible cause or prevention of reoccurring errors. She then submitted the report to the Manager of Clinical and Regulatory Services who "might suggest slight changes." Then it was submitted to corporate electronically. She said she had not received instruction on a root cause analysis process. The facility did not perform comprehensive root cause analysis on incident reports. 2. Incident reports were not analyzed and monitored by the TQM committee.	V 626		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	132530	A. BUILDING _____ B. WING _____	C 06/01/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LEWIS-CLARK KIDNEY CENTER	2116 12TH AVENUE LEWISTON, ID 83501

(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 626	Continued From page 9 A policy titled "Total Quality Management," revised 3/15/16, stated "All incidents are to be discussed at the Total Quality Management meeting. During this meeting, plans need to be formulated for those incidents that could be prevented or reduced." TQM meeting minutes, specific to incident reports, were reviewed for the months of April and May, 2018. The meeting minutes did not show the TQM committee was included in discussion of or in monitoring, assessing or problem solving the incident reports. In a group interview on 5/31/18 at 9:00 AM, the HT RN, MSW, and RD stated attention to incident reports during TQM meetings was "minimal." They said they were not involved in monitoring, assessing or problem solving related to incident reports. They assumed those activities occurred prior to the meetings. They stated the Clinic Manager presented the incident reports to the Medical Director for signature. In an interview on 5/31/18 at 1:00 PM, the Clinic Manager stated she obtained the Medical Directors signature on completed incident reports at TQM meetings. The facility did not include the TQM committee in the incident report process for monitoring, assessing, or resolution.	V 626		
V 634	QAPI-INDICATOR-MEDICAL INJURIES/ERRORS CFR(s): 494.110(a)(2)(vi) The program must include, but not be limited to,	V 634	**V634** The Corporate Clinical Regulatory Manager (CRM) initiated an in-service with all Direct Patient Care (DPC) staff and the Total Quality Management (TQM) Committee on 6/27/2018 to review the reporting requirements for incidents and the type of incidents that must be reported **(see attached in-service record)**. During the in-service it was stressed that all incidents must be documented and reported to the TQM committee to monitor trends and take action to reduce further incidents that impact patient safety. The TQM Risk Managing policy was reviewed which states "Incident Reports are to be completed as soon as possible following an event to ensure that information is recorded accurately. The event needs to be documented noting: • Time of event (pre, post or during treatment) • Location (waiting room, treatment area, parking lot, scale, etc.) • Body part involved	6/27/2018

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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V 634	Continued From page 10 the following: (vi) Medical injuries and medical errors identification. This STANDARD is not met as evidenced by: Based on review of records, policy, incident reports, and staff interview, it was determined the facility failed to ensure accurate patient incident data was gathered and analyzed. This failure directly impacted 1 of 4 ICHD patients (Patient #1) whose records were reviewed, and had the potential to impact all patients in the facility. Failure to gather and analyze accurate incident report information significantly impeded the facility's ability to develop and implement appropriate corrective action plans necessary to minimize the potential for incidents to reoccur. Findings include: A policy titled "Total Quality Management," revised 3/15/16, listed 32 events that required incident reports, required notifications including the Clinic Manager, and required documentation. Patient #1 was a 68 year old female. Treatment records for Patient #1 were reviewed from 5/02/18 - 5/28/18. Her 5/11/18 treatment record showed Patient #1 became unstable immediately post treatment. The record documented tachycardia, altered mental status, inability to stand or ambulate, and decreased oxygen saturation to 80%. Patient #1 was discharged to her SNF in an unstable condition. The record documented the facility nurse informed the SNF Patient #1 and subsequently hospitalized for 6 days.	V 634	• Interventions taken along with the results • Signature of person reporting the incident An incident report is to be completed for the following events: • Cardiac Arrest • Respiratory Arrest • Loss of Consciousness • Seizure • Suspected Air Embolus • Blood loss > 100cc o System separation o System leak o Non-system event o Clotted system • Medication Error o Missed medication o Wrong medication given o Wrong dose given • Allergic Reaction to Medication • Dialyzer Reaction • Incorrect Dialyzer • Incorrect Dialysate • Possible Pyrogen Reaction • Hemolysis • Procedural Variance • Blood Reaction (transfusion) • Infiltration of Access • Clotting of Access • Chest Pain • Unresolved hypo-or hypertension • Events resulting in transfer of patient via ambulance to ER • Equipment/Product Problems related to treatment • Preventative Maintenance not done • Positive cultures >AAMI Standards • Slips	

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V 634	Continued From page 11 Review of incident reports for May, 2018 showed no incident report had been completed for this event. In an interview on 5/31/18 at 1:00 P.M., the Clinic Manager stated the event involving Patient #1 should have generated an incident report. She said she had not been made aware of the event by staff and the event was not included in incident report data. The facility did not collect comprehensive data regarding incident reports for TQM review.	V 634	• Falls • Dirty Needle Sticks o Known source o Unknown source • Exposure to Blood/Body fluids • Exposure to a chemical (inhalation or direct) • Abusive Behavior/Disruptive Behavior • Dermatitis related to job duties (gloves) • Other" All incidents are to be documented on the Incident Report form **(see attached form)** and the Clinic Manager, Attending Physician, Medical Director, and Corporate Clinical Regulatory Manager notified of the event. Once the notifications are completed, the Clinic Manager will gather comprehensive data regarding the incident and review findings with the TQM who will further review the incident and determine root cause analysis and action plans to reduce further incidents. An incident report was completed on Patient #1 on 6/27/18, and will be reviewed by the TQM committee at the next TQM meeting. The clinic manager (CM) will spot check all treatment sheets once a week for a minimum of 12 weeks to identity occurrences of any of the above listed events and that all is documented in the patient's medical record, and an incident report was completed **(See attached CM monitoring tool)**. The Clinic Manager will ensure compliance through completion of the CM monitoring tool and all findings will be addressed at the monthly Total Quality Management (TQM) meeting where additional action will be taken as deemed appropriate by the committee, such as further education, continuing the CM monitoring and/ or disciplinary action.	

IDAHO DEPARTMENT OF
HEALTH & WELFARE

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RUSSELL S. BARRON– Director

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June 18, 2018

Joni Kelley, Administrator
Lewis-Clark Kidney Center
2116 12th Avenue
Lewiston, ID 83501

Provider #132530

Dear Ms. Kelley:

An unannounced on-site complaint investigation was conducted from May 29, 2018 to June 1, 2018 at Lewis-Clark Kidney Center. The complaint allegations, findings, and conclusions are as follows:

Complaint #ID00007845

Allegation #1: Staff do not appropriately respond to patient emergencies.

Findings #1: An unannounced survey was conducted at the facility from 5/29/18 - 6/1/18. Patient treatment records for 4 patients, incident reports, and policies were reviewed. One of the patient treatment records documented an emergency situation, as follows:

The patient was a 68 year old female who resided at a skilled nursing facility. The dialysis facility was aware she had fallen and hit her head prior to coming to the facility for dialysis on 5/11/18. She was accepted by the dialysis facility and dialysis was initiated.

The patient experienced unaddressed tachycardia during her 4 hour dialysis treatment and at the end of her treatment the patient became unstable with altered mental status, a heart rate of 134 beats/minute, and hypoxia with oxygen saturation decreasing to 80%. The physician was notified and gave orders to administer Metoprolol 25 mg. for tachycardia and to return the patient to her

skilled nursing facility for assessment.

The patient was discharged to her skilled nursing facility in unstable condition. The dialysis staff notified the nursing facility that the patient was unstable and would need to be assessed when she arrived.

In an interview on 5/30/18 at 4:00 PM, a Registered Nurse (RN) said he considered calling 911 for the patient, but the physician wanted her to return to her skilled nursing facility. In an interview on 5/30/18 at 2:30 PM, a second RN said she did not have an order to call 911, but did have a physician's order to return the patient to her skilled nursing facility.

However, Idaho Board of Nursing Rule 23.01.01.401.f includes the responsibility of the RN to evaluate patient status and institute appropriate therapy or procedures which may be required in emergency situations.

The facility RNs failed to ensure an emergency situation was addressed appropriately. Therefore, the allegation was substantiated and deficiencies were cited at V100 Condition for Coverage: Compliance with Federal, State, and Local Laws and Regulations and at V101.

Conclusion #1: Substantiated. Federal deficiencies related to the allegation are cited.

Based on the findings of the complaint investigation, deficiencies were cited and included on the survey report. No response is necessary to this complaint report, as it will be addressed in the Plan of Correction.

Thank you for the courtesies extended to us during the survey. If you have any questions, comments or concerns, please contact Dennis Kelly, RN or Nicole Wisenor, Co-Supervisors, Non-Long Term Care at (208) 334-6626, option 4.

Sincerely,

NICOLE WISENOR, Supervisor
Non-Long Term Care

NW/pmt