IDAHO DEPARTMENT OF
HEALTH & WELFARE

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RUSSELL S. BARRON– Director

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April 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:

This is to advise you of the findings of the Medicare survey of Lewis-Clark Kidney Center, which was conducted on April 6, 2018.

Enclosed is a Statement of Deficiencies/Plan of Correction Form CMS-2567, listing Medicare deficiencies. In the spaces provided on the right side of each sheet, please provide a Plan of Correction. It is important that your Plan of Correction address each deficiency in the following manner:

An acceptable plan of correction (PoC) 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 the Form CMS-2567.

After you have completed your Plan of Correction, return the original to this office by **May 2, 2018,** and keep a copy for your records.

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

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 _____	04/06/2018

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LEWIS-CLARK KIDNEY CENTER	2116 12TH AVENUE LEWISTON, ID 83501

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V 000	INITIAL COMMENTS [CORE] The following deficiencies were cited during the recertification survey at your facility from 4/02/18 - 4/05/18. The surveyor conducting the survey was: Trish O'Hara, RN Acronyms used in this report include: AMA - Against Medical Advice AVG - Artero Venous Graft BFR - Blood Flow Rate CM - Clinic Manager CVC - Central Venous Catheter EDW - Estimated Dry Weight ICHD - Incenter Hemodialysis KDOQI HD - Kidney Disease Outcomes Quality Initiative for Hemodialysis kg - kilogram Kt/V - adequacy measure for dialysis ml - milliliter ml/min - milliliter per minute QAPI - Quality Assurance Performance Improvement RN - Registered Nurse TQM - Total Quality Measures	V 000	V 000 The governing body and management staff of this facility takes this deficiency statement very seriously and will ensure that these citations are corrected and that they remain in compliance. The governing body met on 4-24-2018 to review and approve the plan of correction and the tools and updates that will keep approved plan in compliance. The in-services and tools are attached and available for review in the facility.	V 000 4-24-208
V 111	IC-SANITARY ENVIRONMENT CFR(s): 494.30 The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. This STANDARD is not met as evidenced by: Based on observation and staff interview, it was	V 111	RECEIVED APR 27 2018 FACILITY STANDARDS V 111 An in-service was initiated to all Direct Patient Care (DPC) staff on 4-25-2018 by the Clinic Manager (CM) regarding preventing cross contamination. (See attached in-service record) During the in-service emphasis was placed on patients who hold their own sites (or family members/significant others who assist), must wash or sanitize their hands immediately after gloves are removed and before touching any surfaces such as the exit doors, exit door handles or the scale grab bar and before leaving the treatment area. Per Policy: "Patients who hold their own sites must wear gloves. When sites are occluded, gloves are to be removed, and patients instructed to wash their hands before touching equipment and leaving the treatment area." A letter will be given to all patients by the Clinic Manager instructing patients who hold their own sites (or family members/significant others who assist) that they must sanitize their hands before touching any surfaces, such as the exit doors, exit	V 111 4-25-18

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

Toni Kellen — Clinic Manager — 4-25-18

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 111	Continued From page 1 determined the facility failed to provide a sanitary environment. This failure directly impacted 4 of 5 ICHD patients (Patients #8 - #11) observed and had the potential to impact all patients dialyzing at the facility. This resulted in the potential transmission of infection through cross contamination of common surfaces. The findings include: Observations were conducted on 4/04/18 beginning at 8:00 A.M. During the observation Patients #8 - #10 and Patient #11's spouse were noted to hold access needle sites post dialysis. The 4 persons observed wore disposable gloves during the holding process. The 4 persons observed then removed the contaminated gloves but did not perform hand hygiene before leaving the facility. While leaving the facility, the 4 persons were observed to have contact with common surfaces such as exit doors, exit door handles, and the scale grab bar. No disinfection of the common surfaces was noted to occur during the observation. In an interview at the time of the observation, the charge nurse confirmed the lack of hand hygiene and said it should have occurred. The facility failed to provide patients with a sanitary environment.	V 111	door handles or the scale grab bar and before leaving the treatment area by 4-25-2018. (See attached letter) The staff member providing care for the patient is to ensure that the patient (or family member/significant other) sanitizes his/her hands when gloves are removed after holding sites prior to touching any surfaces such as the exit doors, exit door handles or the scale grab bar and before leaving the treatment area. If the patient (or person who assisted) touches objects, such as those listed above, prior to hand sanitization, the surface touched must be immediately cleaned with a 1:100 bleach solution by a staff member and the patient (or family member/significant other) immediately educated on the importance of performing hand sanitization immediately after glove removal. This education should be documented in the medical record. This has been added to the Infection Control Audit (IC) which is normally performed monthly and will now be done weekly for 6 weeks by an assigned DPC staff member (See attached IC audit). The Clinic Manager will also complete one audit per week for 6 weeks. Clinic Manager will ensure compliance through direct observation and through review of the Infection Control Audits. All findings will be addressed at the monthly Total Quality Management (TQM) Meeting and additional action will be taken as deemed appropriate by the committee, such as more education, continuing the weekly audits or if trends are identified, disciplinary action.	
V 543	POC-MANAGE VOLUME STATUS CFR(s): 494.90(a)(1) The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to	V 543	V 543 1, 2, 3, 4 An in-service was initiated to all Direct Patient Care (DPC) staff on 4-25-2018 by the Clinic Manager (CM) stressing that every part of the patient's treatment must be supported by a physician order or justified as to why the order was	V 543 4-25-18

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V 543	Continued From page 2 manage the patient's volume status; This STANDARD is not met as evidenced by: Based on procedure review, staff interview, and clinical record review, it was determined the facility failed to ensure patients' fluid was managed during each treatment for 4 of 6 ICHD patients (Patients #2 - #5) whose treatment records were reviewed. This resulted in the potential for patients to experience complications due to fluid overload between dialysis treatments. The findings include: A facility procedure titled Obtaining Patient Weight, revised 3/29/13, stated "Notify Charge RN if post weight is higher than pre weight or if patient is >1 kg from EDW." There was no further directions to the Charge RN as to what should be done when they received this information. The procedure also stated "Notify attending physician of any variances from estimated dry weight more than 7 kg, weekly or more often if indicated by nursing assessment." It was not clear if a variance from EDW more than 7 kg was a daily value or a cumulative weekly value. Patients did not attain their prescribed EDWs and no remedial actions were implemented, as follows: 1. Patient #2 was a 62 year old female. Eleven treatment sheets, from 3/09/18 - 4/02/18, were reviewed. Patient #2 did not attain her prescribed EDW of 44.5 kg during 10 of 11 treatments as documented by post dialysis weights. DATE POST WT.	V 543	not followed on the treatment record, including estimated dry weights (EDW) and the importance of accurate documentation such as how much the patient is above or below their EDW. (See attached in-service record) During the in-service it was reviewed that If the patient is not achieving their dry weight for 3 consecutive treatments, the physician is to be notified and a new dry weight obtained, if indicated. It was also stressed that if a patient has an excessive weight gain that prevents them from achieving tbeir EDW, the physician must be notified for further orders, such as an extra treatment or extended treatment times. It was also stressed that patient education must occur on fluid management, sodium intake, etc. The physician notification, new physician orders, when indicated and all patient education must be documented in the patient's medical record. It was also stressed that the difference in the post dialysis weight in comparison to the EDW (i.e. how much above or below the patient is compared to their EDW) must be accurately documented in the medical record. All patients' records, including patient # 2-5 have been reviewed to make sure that all dry weights are accurate (i.e. consistently achieving their EDW) and the physician notified if inaccurate (i.e. consistently not achieving their EDW) and new orders obtained if indicated. All corrections have been entered into the computer when indicated. Procedure 2-70 (Obtaining Patient Weight) has been updated to indicate the following: - The charge nurse must is to perform an assessment, provide patient education (such as fluid management) and notify the physician when indicated such as when the patient will not be able to achieve tbeir EDW d/t excessive weight gains, etc. - The physician must be notified if the patient was greater than 1 Kg above their EDW for further orders such as an extra treatment or extended treatment times (post treatment). -The physician must be notified anytime the patient is 1 kg above or below their EDW post dialysis treatment (the weekly reference was removed).	

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V 543	Continued From page 3 3/09/18 45.8 kg 3/14/18 46.0 kg 3/16/18 47.2 kg 3/19/18 47.2 kg 3/21/18 47.3 kg 3/23/18 47.3 kg 3/26/18 48.8 kg 3/28/18 48.2 kg 3/30/18 45.7 kg 4/02/18 46.6 kg There was no documentation showing extra treatment time had been offered, patient education had occurred, or physician notification had been made concerning Patient #2 not attaining her EDW. It was not consistently noted on Patient #2's treatment sheets that her post weights were not +/- 1 kg of prescribed EDW. Documentation on 3/26/18 stated Patient #2's post weight was +/- 1 kg EDW while her actual post dialysis weight showed she was 4.3 kg above her prescribed EDW. Documentation on 3/16/18 stated Patient #2's post weight was +/- 1 kg EDW while her actual post dialysis weight showed she was 2.7 kg above her prescribed EDW. 2. Patient #3 was a 63 year old female. Thirteen treatment sheets, from 3/05/18 - 4/02/18, were reviewed. Patient #3 did not attain her prescribed EDW of 71 kg during 12 of 12 treatments, and EDW OF 72 kg during 1 of 1 treatment, as documented by post dialysis weights. DATE POST WT. 3/05/18 76.5 kg 3/07/18 74.2 kg 3/09/18 74.9 kg	V 543	(See attached Procedure update). The procedure revisions were reviewed during the in-service. The charge nurse (CN) is to round on each shift of patients once they are all on dialysis to ensure that physician orders for EDW's are being followed or that justification has been documented in the medical record as to why the patient could not reach their ordered EDW and the physician notified and other items listed above. The CN will also review each shift of patients' treatment information at the end of the day to ensure that the treatment information is complete and the patient has achieved their EDW. (See attached CN daily round sheet) A tracking tool has been developed to track patients not achieving their dry weights and after 3 treatments, doctor notified, and a new dry weight obtained (See CN monitoring tool for EDW). Additionally, the physician must he notified, prior to the patient's discharge, if a patient's post dialysis weight is above or below their dry weight of 1 Kg or more. This will also be addressed on the patient's Plan of Care if the patient continues to not meet his/her EDW and a plan will be developed by the IDT including the patient to try and meet the goal of the prescribed EDW. The clinic manager will ensure compliance by reviewing the charge nurse rounding tool, the CN monitoring tool for fluid management weekly, and as a member of the Interdisciplinary Team. This form will also be brought to the monthly TQM meeting, of which the Medical Director is a member, for review where additional action will be taken as deemed appropriate hy the committee.	

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V 543	Continued From page 4	V 543		

3/12/18 75.1 kg
3/14/18 75.7 kg
3/16/18 75.8 kg
3/19/18 76.0 kg
3/21/18 74.3 kg
3/23/18 74.6 kg
3/26/18 74.4 kg
3/28/18 75.5 kg
3/30/18 74.5 kg
4/02/18 74.9 kg (EDW 72 kg)

It was consistently noted on Patient #3's treatment sheets that her post weights were not +/- 1 kg of prescribed EDW. However, there was no documentation showing extra treatment time had been offered, patient education had occurred, or physician notification had been made concerning Patient #3 not attaining her EDW.

3. Patient #4 was a 60 year old male. Nine treatment sheets, from 3/07/18 - 4/02/18, were reviewed. Patient #4 did not attain his prescribed EDW of 79.5 kg during 4 of 9 treatments, as documented by post treatment weights.

DATE	POST WT.
3/07/18	80.9 kg
3/12/18	81.2 kg
3/16/18	82.0 kg
3/21/18	82.3 kg

It was consistently noted on Patient #4's treatment sheets that his post weights were not +/- 1 kg of prescribed EDW. However, there was no documentation showing extra treatment time had been offered, patient education had occurred, or physician notification had been made concerning Patient #4 not attaining his EDW.

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V 543	Continued From page 5	V 543		

4. Patient #5 was a 52 year old male. Twelve treatment sheets, from 3/05/18 - 4/02/18 were reviewed. Patient #5 did not attain his prescribed EDW of 101 kg during 12 of 12 treatments, as documented by post treatment weights.

DATE	POST WT.
3/05/18	104.2 kg
3/07/18	102.9 kg
3/12/18	106.0 kg
3/14/18	106.4 kg
3/16/18	104.9 kg
3/19/18	105.6 kg
3/21/18	104.9 kg
3/23/18	106.2 kg
3/26/18	107.9 kg
3/28/18	106.1 kg
3/30/18	105.1 kg
4/02/18	105.4 kg

It was consistently noted on Patient #5's treatment sheets that his post weights were not +/- 1 kg of prescribed EDW. However, there was no documentation showing extra treatment time had been offered or physician notification had been made. Patient education occurred on one occasion, when the RN documented, on 3/15/18, "Pt. advised to moderate his fluid, Sodium and Potassium intake."

In an interview on 4/05/18 at 11:00 A.M., the CM confirmed Patients #2 - #5 had not attained their EDWs. She said extra treatment time was not available to patients at the facility because the facility only operated on a Monday/Wednesday/Friday schedule. When asked, she said if a patient needed extra treatment time for fluid removal, it would be possible to have a dialysis treatment at the local

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V 543	Continued From page 6 hospital performed by the acute dialysis team. In an interview on 4/04/18 at 4:00 P.M., the charge nurse said if a patient needed extra treatment time for fluid removal, nurses could offer them another treatment on the same day on another shift. In a telephone interview on 4/11/18 at 11:00 A.M., the CM stated she was not aware of a policy that addressed patients attaining their EDW. However, she said the issue was addressed on each treatment sheet. Post treatment data collection included the question "Post Weight within 1 kg =/- EDW." The RN had the option to respond yes or no. Volume status was not managed for Patients #2 - #5.	V 543		
V 544	POC-ACHIEVE ADEQUATE CLEARANCE CFR(s): 494.90(a)(1) Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. This STANDARD is not met as evidenced by: Based on record review, and staff interview, it was determined the facility failed to ensure each patient's prescribed dose of dialysis was delivered as ordered and decreased adequacies were addressed. This directly impacted 5 of 6 ICHD patients (Patients #1, #2, #4, #5 and #6) and had the potential to impact all patients dialyzing at the facility, by placing them at risk for	V 544	V 544 1 a, b, c, d An in-service for all DPC staff was initiated by the Clinic Manager on 4-25-2018 reinforcing that every part of the dialysis prescription has to be supported by a physician order or justified in writing on the treatment record as to why the orders was not met. (See attached in-service record) This includes the Blood Flow Rate (BFR). If BFR cannot be achieved as ordered, documentation to that effect needs to appear on the treatment record with the reason that the prescribed BFR could not be obtained. If the BFR cannot be obtained due to reasons such as machine alarms and/or high venous pressures, an assessment must be performed by the nurse and interventions such as needle adjustments performed and documented. If the BFR cannot be consistently maintained as ordered, the physician needs to be notified and documentation to this effect placed on the medical record. If possible, new	V 544 4-25-18

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V 544	Continued From page 7 complications of decreased adequacy and access complications. The findings include: 1. Patients' prescribed BFRs were not maintained and decreased adequacies were not addressed as follows: a. Patient #5 was a 52 year old male who dialyzed using a CVC. Twelve treatment sheets, from 3/05/18 - 3/30/18 were reviewed. His prescribed BFR of 450 ml/min was not maintained as follows: 3/05/18 - BFR was 400 ml/min for the duration of the treatment. 3/07/18 - BFR was 350 ml/min for the duration of the treatment. 3/12/18 - BFR was 350 - 400 ml/min for the duration of the treatment. 3/14/18 - BFR was 250 - 300 ml/min for the duration of the treatment. 3/16/18 - BFR was 300 - 350 ml/min for the duration of the treatment. 3/19/18 - BFR was 400 ml/min during 50% of the treatment time. 3/21/18 - BFR was 350 ml/min for the duration of the treatment. 3/23/18 - BFR was 400 ml/min for the duration of the treatment. 3/26/18 - BFR was 350 ml/min for the duration of the treatment. 3/28/18 - BFR was 400 ml/min for the duration of the treatment. 3/30/18 - BFR was 350 ml/min for the duration of the treatment. 4/02/18 - BFR was 350 ml/min for 75% of the treatment time with a nursing note stating "BFR turned down. Perscription [sic] not correct."	V 544	orders need to be obtained for an alternate BFR or for vascular access referral, at the discretion of the physician. If the BFR is continually not being met or the patient is not achieving the desired Kt/V of 1.2 or more (hemodialysis), this requires the interdisciplinary team to complete a Comprehensive Assessment and develop a Plan of Care (CA/POC). Interventions (such as Vascular Access referrals, extended treatment times, etc.) need to be identified and goals set to try to achieve the desired BFR and the meet the desired Kt/V of at least 1.2 (hemodialysis). The Charge Nurse (CN), after each shift of patients is on dialysis, is to round on each patient (a minimum of twice per shift) to make sure that they are receiving the prescribed BFR as ordered. (See attached CN Rounding Tool) If they are not achieving the ordered BFR, there must be documentation in place to support and justify why the prescribed BFR is not being obtained or maintained as well as interventions (such as needle adjustment) to try to achieve the prescribed BFR. After each shift of patients has completed their treatments, the Nurse in Charge is to review the treatment information at the end of the day to ensure the patient ran on the correct BFR for the entire treatment. The Clinic Manager will ensure compliance through review of this rounding tool and will also review one day of treatment records weekly for 6 weeks to ensure that the BFR is being delivered as prescribed or justified. The clinic manager will also review all monthly Kt/V results of all hemodialysis patients to ensure the goal of 1.2 is being met. If not, the Clinic Manager will perform an investigation, which will include assessment of the prescribed BFR, treatment times, etc. (See attached CM Monitoring Tool) The information for the Kt/V will be recorded on the CM monitoring tool monthly for 6 months and included in the TQM minutes thereafter. All findings from the CN and CM tools will be brought to the monthly TQM meeting, of which the medical director is a member for review and further action will be taken as deemed appropriate such as continued monitoring and/or disciplinary action.	

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V 544	Continued From page 8 Documentation showed BFR had been decreased during 5 treatments due to machine alarms. However, no documentation was present showing Patient #5's access patency had been assessed during this 25 day period. Additionally, Patient #5's Kt/V, indicating dialysis adequacy, was documented as 1.08 on 3/2018 monthly lab results. KDOQI HD, 2006, recommends adequacy be maintained >/= 1.2. No changes in treatment were noted as a result of the decreased adequacy. b. Patient #2 was a 62 year old female who dialyzed using a CVC. Twelve treatment sheets, from 3/07/18 - 4/02/18 were reviewed. Her prescribed BFR of 350 ml/min was not maintained as follows: 3/12/18 - BFR was 200 ml/min for the first 2 hours of her 3 hour treatment. BFR was then increased to 400 ml/min for the last 30 minutes of treatment. 3/16/18 - BFR was 200 ml/min for 55 minutes of treatment. 3/23/18 - BFR was 400 ml/min for 2 hours of treatment. No documentation was present indicating why prescribed BFR was not maintained. c. Patient #1 was a 47 year old male who dialyzed using a CVC. Thirteen treatment sheets, from 3/05/18 - 4/02/18 were reviewed. His prescribed BFR of 400 ml/min was not maintained as follows: 3/05/18 - BFR was 350 ml/min for the duration of treatment.	V 544	2 a, b, c, d An in-service was initiated to all Direct Patient Care (DPC) staff and the IDT team on 4-25-2018 by the Clinic Manager to reinforce that the duration of the dialysis treatment must be followed per physician order. (See attached in-service record) Per policy: "An Against Medical Advice (AMA) form must be completed and signed by the patient each time that the patient requests that the prescribed treatment time be shortened. Documentation must also be made on the patient's treatment sheet. If this is a repeated request, it becomes a problem that must be discussed at the monthly care plan meetings." During the in-service it was stressed that the reason for shortening the treatment must be documented so the Interdisciplinary Team (IDT) can identify any barriers preventing the patient from completing their prescribed treatment. It was also stressed that the physician must be notified anytime a patient misses more than 10 minutes of their prescribed time so alternate orders such as making up the treatment time can be considered, at the physician's discretion. This notification and orders, when indicated, must be documented in the patient's medical record. The charge nurse (CN) is to review the treatment information at the end of the day to ensure that all treatment times are completed per physician order or the reason documented and that when patients choose to shorten their treatment time an AMA form is signed each time with the reason for the shortened treatment documented and physician notification documented when greater than 10 minutes. (See attached CN daily round sheet) It was also stressed that patterns of noncompliance or inability to achieve the Kt/V of 1.2 or more (hemodialysis) must be included in the Comprehensive Assessment and Plan of Care (CA/POC) where a plan must be formed with goals set to achieve compliance and/or the desired Kt/V. The Clinic Manager will ensure compliance through review of this rounding tool and will also review one day of treatment records weekly for 6 weeks to	

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	132530	A. BUILDING _____ B. WING _____	04/06/2018

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V 544	Continued From page 9 3/09/18 - BFR was 300-350 ml/min for the duration of the treatment. 3/12/18 - BFR was 260-350 ml/min for the duration of the treatment. Documentation showed BFR had been decreased during 2 treatments due to machine alarms. However, no documentation was present showing Patient #1's access patency had been assessed. d. Patient #4 was a 60 year old male who dialyzed using a left thigh AVG. Nine treatment sheets, from 3/07/18 - 4/02/18 were reviewed. His prescribed BFR of 400 ml/min was not maintained as follows: 3/07/18 - BFR was 200 ml/min for 1 hour of the treatment. 3/26/18 - BFR was 350 ml/min for the duration of the treatment. 3/30/18 - BFR was 325-380 ml/min for 3 hours of the treatment. Documentation showed BFR had been decreased during 1 treatment due to increased venous needle pressure. However, no documentation was present showing attempted resolution of the problem. Additionally, Patient #4's Kt/V, indicating dialysis adequacy, was documented as 0.98 on 3/2018 monthly lab results. KDOQI HD 2006 recommends adequacy be maintained >/= 1.2. No changes in treatment were noted as a result of the decreased adequacy. In an interview on 4/05/18 at 11:00 A.M., the CM confirmed BFRs had not been maintained and	V 544	ensure that the prescribed treatment time is being delivered as prescribed or justified. The clinic manager will also review all monthly Kt/V results of all hemodialysis patients to ensure the goal of 1.2 is being met. If not, the Clinic Manager will perform an investigation, which will include assessment of the prescribed BFR, treatment times, etc. (See attached CM Monitoring Tool) The information for the Kt/V will be recorded on the CM monitoring tool monthly for 6 months and included in the TQM minutes thereafter. All findings from the CN and CM tools will be brought to the monthly TQM meeting, of which the medical director is a member for review and further action will be taken as deemed appropriate such as continued monitoring and/or disciplinary action.	

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V 544	Continued From page 10 decreased adequacies had not been addressed. 2. Patients' prescribed dialysis treatment times were not delivered as follows: a. Patient #6 was a 33 year old male. Thirteen treatment sheets, from 3/05/18 - 4/02/18, were reviewed showing a prescribed dialysis treatment time of 240 minutes. His treatment time was shortened by 10 minutes on 3/16/18, by 5 minutes on 3/26/18, by 5 minutes on 3/30/18, and by 8 minutes on 4/02/18. No documentation was present indicating why the 4 treatments were not delivered as prescribed, or indicating an opportunity to make up 28 minutes of lost time was offered to Patient #6. b. Patient #2 was a 62 year old female. Twelve treatment sheets were reviewed, from 3/07/18 - 4/02/18, showing a prescribed dialysis time of 180 minutes. Her treatment time was shortened by 5 minutes on 3/09/18, by 18 minutes on 3/19/18, by 28 minutes on 3/26/18, and by 50 minutes on 3/30/18. Documentation was present indicating Patient #2 signed an AMA form, voluntarily terminating her treatment early, on 3/26/18 and 3/30/18. However, no documentation was present on the 4 treatment sheets indicating an opportunity to make up lost time was offered to Patient #2. c. Patient #4 was a 60 year old male. Nine treatment sheets, from 3/07/18 - 4/02/18, were	V 544		

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V 544	Continued From page 11 reviewed showing a prescribed treatment time of 240 minutes. His treatment time was shortened by 122 minutes on 3/12/18, by 29 minutes on 3/16/18, by 16 minutes on 3/21/18, and by 29 minutes on 3/26/18. Documentation showed Patient #4 signed an AMA form, voluntarily terminating his treatment early on 3/12/18 and 3/21/18. No documentation was present explaining why his treatments were shortened on 3/16/18 and 3/26/18. Additionally, there was no documentation present on the 4 treatment sheets indicating an opportunity to make up lost time was offered to Patient #4. d. Patient #5 was a 52 year old male. Twelve treatment sheets, from 3/05/18 - 3/30/18 , were reviewed showing a treatment time of 210 minutes. His treatment time was shortened by 54 minutes on 3/05/18, by 12 minutes on 3/07/18, by 17 minutes on 3/14/18, and by 70 minutes on 3/23/18. Documentation showed Patient #5 signed an AMA form, voluntarily terminating his treatments early, on 3/05/18, 3/07/18, 3/14/18, and 3/23/18. However, there was no documentation present on the 4 treatment sheets indicating an opportunity to make up lost time was offered to Patient #5. In an interview on 4/05/18 at 11:00 A.M., the CM confirmed the shortened treatment times for	V 544		

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V 544	Continued From page 12 Patients #2, #4, #5 and #6. She stated loss of patient treatment time was tracked by TQM, the facility's QAPI process. The facility failed to ensure the prescribed dose of dialysis was delivered to Patients #2, #4, #5, and #6.	V 544		
V 634	QAPI-INDICATOR-MEDICAL INJURIES/ERRORS CFR(s): 494.110(a)(2)(vi) The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification. This STANDARD is not met as evidenced by: Based on review of adverse event reports, medical record review, AMA data review, and staff interview, it was determined the facility failed to ensure accurate patient adverse event data and AMA data was gathered and analyzed. This failure directly impacted 2 of 25 dialysis machines whose maintenance records were reviewed, and 3 of 6 patients (Patients #1, #2 and #4) whose records were reviewed. Failure to gather and analyze accurate adverse event information and AMA data significantly impeded the facility's ability to develop and implement appropriate corrective action plans necessary to minimize the potential for adverse events and AMAs to re-occur. The findings include: The facility's QAPI committee was identified as the TQM committee. 1. Adverse event data collection was not	V 634	V 634 1 a, b An in-service was initiated to all Direct Patient Care (DPC) Staff and the Total Quality Management (TQM) committee on 4-25-2018 by the corporate clinical and regulatory manager regarding the importance of the completion of incident reports for machine related events. (See attached in-service record) During the in-service it was stressed, in order to perform a root cause analysis and identify any trends and develop action plans to prevent re-occurrence, anytime a machine event is identified, including the potential of inaccurate fluid removal, an incident report must be completed (in addition to the maintenance request). This report will require the investigation of the problem and any potential negative effect on the patient. During the in-service the incident report form was reviewed. Per Policy: "Incident Reports are required for events that occur in relation to a dialysis treatment or procedure, exposure to pathogens or chemicals, staff or patient events related to a medical device, serious events..." Also per policy: "An incident report is to be completed for the following events: • Equipment/Product Problems related to treatment" The clinic manager will ensure compliance by reviewing all Equipment Service Request Forms monthly for the next 6 months to ensure incident reports were completed for all treatment related events, including the potential for inaccurate fluid	V 634 4-25-18

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V 634	Continued From page 13 comprehensive as follows: a. An Equipment Service Request Form, dated 12/29/17, reported an unidentified patient's post dialysis weight showed no fluid removal during treatment, while the machine had recorded specific fluid removal amounts during 2 treatments. Preventive maintenance was performed on the machine on 1/03/18. A second Equipment Service Request Form, dated 1/05/18, reported the same machine had been programmed to remove 4500 ml during an unidentified patient's treatment, but the patient's post weight reflected a weight gain of 700 ml during treatment. The request form stated the patient was recannulated and placed back on the machine for fluid removal. Maintenance logs showed the machine was recalibrated on 1/15/18. No adverse event report was available for this event indicating an investigation was done or the patient was identified and assessed for injury. b. An equipment Service Request Form, dated 12/17/16, stated "Machine will not pass blood leak during treatment." Maintenance logs showed the machine was recalibrated on 12/19/16. No adverse event report was available for this event indicating an investigation was done or the patient was identified and assessed for injury.	V 634	removal and will ensure this information is tracked and trended by the TQM committee where a root cause analysis will he performed and action plan developed. (See attached CM monitoring tool). The findings from the CM monitoring tool and all incident reports will be brought to monthly TQM meeting for review where further action will be taken by the committee such as continuing the CM monitoring and/or disciplinary action. 2 a, b, c An in-service was initiated to all Direct Patient Care (DPC) Staff and the Total Quality Management (TQM) committee on 4-25-2018 by the corporate clinical and regulatory manager regarding the importance accurately documenting shorted treatment times (AMA's) in the computer system. (See attached in-service record). During the in-service it was stressed that AMA must he selected in the drop down box so the information will be included in the treatment disposition report so it can be tracked and trended and action plans developed when trends are identified by the TQM committee. During the in-service it was stressed that early termination of treatment is an important component of the TQM program and the information must be accurately entered so it can be included in the TQM program. The charge nurse (CN) is to review the treatment records at the end of the day to ensure that all treatment times are completed per physician order or the reason documented and that when patients choose to shorten their treatment time an AMA form is signed each time with the reason for the shortened treatment documented and physician notification documented when greater than 10 minutes. (See attached CN daily round sheet) The charge nurse will also ensure that the AMA was entered accurately into the computer system so the information can be included in the treatment disposition report and captured in the TQM program. The Clinic Manager will ensure compliance through review of this rounding tool	

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V 634	Continued From page 14 In an interview on 4/05/18 at 11:00 A.M., the CM stated adverse event reports should have been created for the machine events and investigation should have occurred. 2. Inaccurate AMA data collection included, but was not limited, to the following: a. Patient #4 was a 60 year old male. Treatment sheets for 3/12/18, 3/16/18, and 3/26/18 documented the treatments were voluntarily shortened by the patient. A cumulative 180 minutes of treatment time was lost. The HD FlowSheet Disposition Tracking Report for March, 2018 did not include these events. b. Patient #5 was a 52 year old male. Treatment sheets dated 3/05/18 and 3/07/18 documented the treatments were voluntarily shortened by the patient. A cumulative 66 minutes of treatment time was lost. The HD FlowSheet Disposition Tracking Report for March, 2018 did not include these events. c. Patient #2 was a 62 year old female. The HD Flowsheet Disposition Tracking Report for March, 2018 showed she has shortened her treatment voluntarily on 3/12/18. Review of the treatment sheet for 3/12/18 documented her treatment as 2 minutes longer than prescribed, according to machine data. Nursing documentation showed Patient #2 had voluntarily terminated her treatment early. In an interview on 4/05/18 at 11:00 A.M., the CM stated AMA information for the HD Flowsheet Disposition Tracking Report was collected from post dialysis data entered by staff on each treatment sheet. She stated the post treatment	V 634	and will also review one day of treatment records weekly for 6 weeks to ensure that all AMA's are accurately documented in the computer so the information is included in the TQM program. (See attached CM Monitoring Tool) All findings from the CN and CM tools will he brought to the monthly TQM meeting, of which the medical director is a member for review and further action will be taken as deemed appropriate such as continued monitoring and/or disciplinary action.	

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V 634	Continued From page 15 data collection area marked "Disposition" had a drop down box offering options for patient discharge. If the option "Signed off early (AMA)" was not appropriately entered by staff, the event would not be captured on the HD Flowsheet Disposition Tracking Report for review by the TQM committee. Data related to adverse events and AMA events was not comprehensively collected for TQM review.	V 634		