IDAHO DEPARTMENT OF
HEALTH & WELFARE

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

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DIVISION OF LICENSING & CERTIFICATION
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BUREAU OF FACILITY STANDARDS
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August 30, 2016

Rod Jacobson, Administrator
Bear Lake Dialysis Center
164 South 5th Street
Montpelier, ID 83254

RE: Bear Lake Dialysis Center, Provider #132304

Dear Mr. Jacobson:

Based on the survey completed at Bear Lake Dialysis Center, on August 19, 2016, by our staff, we have determined Bear Lake Dialysis Center is out of compliance with the Medicare ESRD **Conditions for Coverage (CfC) of Water & Dialysate Quality (42 CFR 494.40), CFC Responsibilities of the Medical Director (42 CFR 494.150) and CFC Governance (42 CFR 494.180)**. To participate as a provider of services in the Medicare Program, a OR 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 Bear Lake Dialysis 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 October 3, 2016. To allow time for a revisit to verify corrections prior to that date, it is important that the completion dates on your Credible Allegation/Plan of Correction show compliance no later than September 14, 2016.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **September 12, 2016**.

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

We urge you to begin correction immediately.

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
CMS Region X Office

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	132304	A. BUILDING _____ B. WING _____	08/19/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BEAR LAKE DIALYSIS CENTER	164 SOUTH 5TH STREET MONTPELIER, ID 83254

(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	V 000		

CORE

The following deficiencies were cited during the recertification survey of your ESRD facility from 8/17/16 - 8/19/16. The surveyor conducting the survey was:
Trish O'Hara, RN

Acronyms used in this report include:

AAMI - Association for the Advancement of Medical Instrumentation
CC - Colony Count
CFU - Colony Forming Units
EDW - Estimated Dry Weight
ICHD - Incenter Hemodialysis
LAL - Limulus Amoebocyte Lysate
ml - milliliter
QAPI - Quality Assurance Performance Improvement
RO - Reverse Osmosis

Immediate Jeopardy was identified at V178, V180, and V254 and the facility was notified on 8/19/16 at 9:30 a.m. The facility submitted an immediate Plan of Correction on 8/19/16 at 12:00 p.m. and the Immediate Jeopardy was removed at 8/19/16 at 1:00 p.m.

V 126 494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF — V 126

See page 2 of 20

Hepatitis B Vaccination

Vaccinate all susceptible patients and staff members against hepatitis B.

This STANDARD is not met as evidenced by:
Based on staff interview and clinical record

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

Tod Paulson | CFO | 9-9-16

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.

Tod Paulson

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V 126	Continued From page 1 review, it was determined the facility failed to ensure Hepatitis B vaccinations were offered, in an appropriate timeframe, to 1 of 3 patients (Patient #1), whose records were reviewed. This failure put a patient at risk of acquiring a communicable disease. The findings include: Patient #1 was a 65 year old female who had been dialyzing at the facility for four months, since 4/18/16. Review of Patient #1's serum lab values showed she did not have antibodies indicating immunity to Hepatitis B. Review of her clinical record showed no documented administration of Hepatitis B vaccinations. The record contained no documentation that Patient #1 had been offered the vaccination series. In an interview on 8/19/16 at 7:30 a.m., the facility's vaccination nurse said she was unaware Patient #1 had not been offered the Hepatitis B vaccination series. When asked, she said she was not aware of a facility policy clarifying when the vaccination should have been offered or initiated. In an interview on 8/18/16 at 5:00 p.m., the Administrator confirmed there was no policy specifying when the vaccination series should have been offered or initiated. The facility failed to offer Patient #1 Hepatitis B vaccinations in an appropriate timeframe.	V 126	Policy has been written and approved for the administration of the Hepatitis B vaccine (see Exhibit A) defining when it needs to be initiated and clearly outlining when the entire series needs to be given. We also added a refusal section to the Hepatitis B consent form (see Exhibit B) for the patient to fill out if vaccine is refused and this will be part of their vaccination record in their chart. Nursing staff have reviewed this policy and have been educated on obtaining the consent and administration of the vaccine.	09/08/16
V 175	494.40 CFC-WATER & DIALYSATE QUALITY This CONDITION is not met as evidenced by: Based on staff interview and laboratory results, it	V 175	See page 3 of 20	

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V 175	Continued From page 2 was determined the facility failed to ensure the delivery of safe product water for patient dialysis treatments. This failure placed all facility patients in immediate jeopardy of severe harm, injury, or death. Findings include: 1. Refer to V178 as it relates to the facility's failure to provide action when product water showed a viable microbial level above AAMI recommended levels. 2. Refer to V180 as it relates to the facility's failure to provide action when dialysate showed a viable microbial level above AAMI recommended levels. 3. Refer to V254 as it relates to the facility's failure to collect water and dialysate for microbial testing immediately prior to water system disinfection.	V 175	Agreement between Medical Director, Nurse Administrator and the biomed tech has been signed and a scheduled date for water testing and disinfection has been assigned (see Exhibit C). Policy concerning drawing of water samples, disinfecting system and notification has been written (see Exhibit D). A notification and conversation log has been created as well for staff to document communication with the Biomed Tech and Medical Director in for water testing concerns, machine concerns and RO room concerns (see Exhibit E, F and G).	09/08/16
V 178	494.40(a) BACT OF H20-MAXIMUM & ACTION LEVELS 4.1.2 Bacteriology of water: max & action levels Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL The action level for the total viable microbial count in the product water shall be 50 CFU/mL, and the action level for the endotoxin concentration shall be 1 EU/mL. If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels.	V 178		

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V 178	Continued From page 3	V 178	See page 3 of 20	

This STANDARD is not met as evidenced by:
Based on water system laboratory reports and staff interview, it was determined the facility failed to ensure corrective action was taken when water samples showed a viable microbial count greater than 50 CFU/ml. This failure compromised patient safety and placed 6 of 6 current patients (Patients #1 - #6) and 1 of 1 patients (Patient #7) who was dialyzing at the time of the occurrence but whose last treatment was 6/8/16, at risk of negative outcomes including, but not limited to, pyrogenic reaction. The findings include:

In an interview on 8/18/16 at 5:00 p.m., the Administrator said she routinely collected CC and LAL water samples on the first Monday or Tuesday of each month. Dialysate samples were collected the following day. The results were transmitted to the facility from the laboratory on Wednesday or Thursday of the same week. If the results showed the presence of bacteria, the Administrator contacted the biomedical technician for instructions.

1. On 5/3/16 water samples were collected from the bicarbonate mixer, the beginning of the RO loop, the end of the RO loop, and dialysis machine #480. Results, returned on 5/5/16, verified bacterial colony counts in all four areas as being >600 CFU/ml. The Administrator contacted the biomedical technician and she was told, by the technician, to redraw the samples.

The samples were redrawn on 5/10/16. Results, returned to the facility on 5/12/16, showed continued bacterial contamination at levels >600 CFU/ml at all collection points.

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V 178	Continued From page 4	V 178	See page 3 of 20	

The biomedical technician was again notified and he disinfected the water system on 5/14/16, according to the Water Treatment System Maintenance log.

However, Patients #1 - #7 continued to dialyze on 5/6/16, 5/9/16, 5/11/16, and 5/13/16 while the water system was known to be contaminated, as shown by the repeated sample results.

In an interview on 8/19/16 at 11:00 a.m., the Medical Director said he was made aware of the occurrence at the monthly QAPI meeting on 6/24/16.

In an interview on 8/19/16 at 8:30 a.m., the biomedical technician confirmed the occurrence. He said he was aware the Medical Director should have been notified but he thought the Administrator made the notification.

In an interview on 8/18/16, the Administrator confirmed the occurrence. She said there was no policy in place requiring Medical Director notification. During her orientation to the facility, she was told to contact the biomedical technician.

2. On 6/7/16 water samples were drawn from the bicarbonate mixer, the beginning of the RO loop, the end of the RO loop, and dialysis machine #420. Results returned on 6/9/16 verified bacterial colony counts in all four areas as being >600 CFU/ml. The Administrator contacted the biomedical technician and the water system was disinfected on 6/10/16, according to the Water Treatment System Maintenance log reviewed.

Water samples were again collected, from the

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V 178	Continued From page 5	V 178	See page 3 of 20	

same four points, on 6/16/16. Results returned to the facility on 6/18/16 showed continued bacterial contamination at all points, ranging from 132 - 148 CFU/ml. The water system was disinfected on 7/9/16 according to the Water Treatment System Maintenance log.

However, Patients #1 - #6 continued to dialyze on 6/20/16, 6/22/16, 6/24/16, 6/27/16, 6/29/16, 7/1/16, 7/4/16, 7/6/16, and 7/8/16, a total of nine treatment days while the water system was known to be contaminated.

In an interview on 8/19/16 at 11:00 a.m., the Medical Director said he was made aware of the occurrence at the monthly QAPI meeting on 7/25/16.

In an interview on 8/19/16 at 8:30 a.m., the biomedical technician confirmed the occurrence but said he was not aware of the continued water system contamination as shown by the 6/16/16 culture results.

In an interview on 8/18/16, the Administrator confirmed the occurrence. She said there was no policy in place requiring Medical Director notification. She said the biomedical technician had been notified of the 6/16/16 culture results. A handwritten note by the Administrator on the lab result sheet stated "[biomedical technician's name] was notified of these levels and will disinfect loop and RO again." She said the technician came, from another city, after clinic hours so she was not always aware the disinfection had been done. She said she routinely communicated with the biomedical technician via text message and there was no written documentation of communication.

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V 178	Continued From page 6 Review of facility Policy and Procedures showed no document providing an action plan for positive bacterial cultures. The facility failed to provide corrective action in response to water system contamination. Note: The facility was notified of an Immediate Jeopardy on 8/19/16 at 9:30 a.m. The facility submitted a Plan of Correction on 8/19/16 at 12:00 p.m. which stated, in the event of positive water CCs or LALs the Medical Director would be notified and would determine whether patients could dialyze safely at the facility or would be diverted for treatment. The plan stated disinfection of the water system would be performed the same night the positive lab results were received by the facility. The plan stated the corrective action would be implemented on 8/19/16. The plan's implementation was verified by signatures of understanding by the Administrator, Medical Director, and the biomedical technician. On-site verification of the plan's implementation was completed on 8/19/16 at 1:00 p.m. and the Immediate Jeopardy was removed.	V 178	See page 3 of 20	
V 180	494.40(a) BACT CONVENT DIALYSATE-MAX & ACTION LEVELS 4.3.2.1 Bacteriology of conventional dialysate: max & action limits Conventional dialysate should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration of lower than 2 EU/mL. The action level for the total viable microbial	V 180	See page 3 of 20	

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count in conventional dialysate should be 50 CFU/mL and the action level for the endotoxin concentration should be 1 EU/mL. If levels exceeding the action levels are observed in the dialysate, corrective measures, such as disinfection and retesting, should promptly be taken to reduce the levels.

This STANDARD is not met as evidenced by:
Based on dialysate sample laboratory reports and staff interview, it was determined the facility failed to ensure corrective action was taken when dialysate samples showed a viable microbial count greater than 50 CFU/ml. This failure compromised patient safety for 6 of 6 current patients (Patients #1 - #6) and 1 of 1 patients (Patient #7) who was dialyzing at the time of the occurrence but whose last treatment was 6/8/16, by placing them at risk of negative outcomes including pyrogenic reaction. The findings include:

In an interview on 8/18/16 at 5:00 p.m., the Administrator said she routinely collected CC and LAL dialysate samples on the first Monday or Tuesday of each month. The results were transmitted to the facility from the laboratory on Wednesday or Thursday of the same week. If the results showed the presence of bacteria, the Administrator contacted the biomedical technician for instructions.

1. On 5/4/16 dialysate samples were drawn from machine #377 (the beginning of the RO loop,) machine #353 (the end of the RO loop,) and dialysis machine #480. Results, returned on 5/6/16, verified bacterial colony counts in all three machines as being >600 CFU/ml. The Administrator contacted the biomedical technician

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V 180	Continued From page 8	V 180	See page 3 of 20	

and she was told, by the technician, to redraw the samples.

The samples were redrawn on 5/10/16. Results, returned to the facility on 5/12/16, showed continued bacterial contamination in all three machines continued at levels >600 CFU/ml.

The biomedical technician was again notified and he disinfected the water system on 5/14/16, according to the Water Treatment System Maintenance log.

However, Patients #1 - #7 continued to dialyze on 5/6/16, 5/9/16, 5/11/16, and 5/13/16 while the dialysate was known to be contaminated.

Dialysate samples drawn on 5/16/16 were negative for machine #377 (the beginning of the loop) and machine #353 (the end of the loop.) However, machine #480 remained above action level at 62 CFU/ml. No further corrective action was taken with this machine.

In an interview on 8/19/16 at 11:00 a.m., the Medical Director said he was made aware of the occurrence at the monthly QAPI meeting on 6/24/16.

In an interview on 8/19/16 at 8:30 a.m., the biomedical technician confirmed the occurrence. He said he was aware the Medical Director should have been notified but he thought the Administrator made the notification.

In an interview on 8/18/16, the Administrator confirmed the occurrence. She said there was no policy in place requiring Medical Director notification. During her orientation to the facility,

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she was told to contact the biomedical technician.

2. On 6/7/16 dialysate samples were drawn from machine #377 (the beginning of the RO loop,) machine #353 (the end of the RO loop,) and dialysis machine #420. Results, returned on 6/9/16, verified bacterial colony counts in all three machines as being 472 - >600 CFU/ml. The Administrator contacted the biomedical technician and the water system was disinfected on 6/10/16 according to the Water Treatment System Maintenance log.

Dialysate samples were again collected, from the same three points, on 6/15/16. Results, returned to the facility on 6/18/16, showed continued bacterial contamination at all three points, ranging from 82 - 126 CFU/ml. The water system was disinfected on 7/9/16 according to the Water Treatment System Maintenance log.

However, Patients #1 - #6 continued to dialyze on 6/20/16, 6/22/16, 6/24/16, 6/27/16, 6/29/16, 7/1/16, 7/4/16, 7/6/16, and 7/8/16, a total of nine treatment days, while the water system was known to be contaminated.

In an interview on 8/19/16 at 11:00 a.m., the Medical Director said he was made aware of the occurrence at the monthly QAPI meeting on 7/25/16.

In an interview on 8/19/16 at 8:30 a.m., the biomedical technician confirmed the occurrence, but said he was not aware of the continued water system contamination as shown by the 6/16/16 culture results and did not perform addition disinfection at the time.

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In an interview on 8/18/16 at 5:00 p.m., the Administrator confirmed the occurrence. She said there was no policy in place requiring Medical Director notification. She said the biomedical technician had been notified. A handwritten note by the Administrator on the lab result sheet stated "[biomedical technician's name] was notified of these levels and will disinfect loop and RO again." She said the technician came from another city after clinic hours, so she was not always aware the disinfection had been done. She said she routinely communicated with the biomedical technician via text message and there was no written documentation of communication.

Review of facility Policy and Procedures showed no document providing an action plan for positive bacterial cultures in dialysate.

The facility failed to provide corrective action in response to dialysate contamination.

Note: The facility was notified of an Immediate Jeopardy on 8/19/16 at 9:30 a.m. The facility submitted a Plan of Correction on 8/19/16 at 12:00 p.m. which stated, in the event of positive dialysate CCs or LALs the Medical Director would be notified and would determine whether patients could dialyze safely at the facility or would be diverted for treatment. The plan stated disinfection of the water system would be performed the same night the positive lab results were received by the facility. The plan stated the corrective action would be implemented on 8/19/16. The plan's implementation was verified by signatures of understanding by the Administrator, Medical Director, and the biomedical technician. On-site verification of the

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 180	Continued From page 11 plan's implementation was completed on 8/19/16 at 1:00 p.m. and the Immediate Jeopardy was removed.	V 180	See page 3 of 20	
V 254	494.40(a) MICROB MONITOR-SAMPLE BEFORE DISINFECT 7.2 Microbial monitoring methods 7.2.1 General: samples before disinfect Samples should always be collected before sanitization/disinfection of the water treatment system and dialysis machines. This STANDARD is not met as evidenced by: Based on staff interview, laboratory results review, and maintenance log review, it was determined the facility failed to ensure water and dialysate samples were collected, for microbial monitoring, immediately prior to water system disinfection. This failure placed 7 of 7 patients (Patients #1 - #7) at risk of bacterial contamination for extended periods of time. The findings include: Review and comparison of sample collection dates and water system disinfection dates showed the following: Collection Date — Disinfection Date 2/1/16 — 2/27/16 3/8/16 — 3/19/16 4/4/16 — 4/16/16 5/3/16 — 5/14/16	V 254	See page 3 of 20	

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	132304	A. BUILDING _____ B. WING _____	08/19/2016

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V 254	Continued From page 12	V 254	See page 3 of 20	

6/6/16 6/10/16

7/6/16 7/9/16

8/2/16 not performed as of 8/19/16

Five of seven water system disinfections were not done in close time proximity after water and dialysate sampling, as recommended by AAMI standards.

AAMI standards, RD52:2004, stated "samples must be collected in the 'worst case' scenario: before sanitation and disinfection..."

In an interview on 8/18/16 at 5:00 p.m., the Administrator said she routinely collected water and dialysate samples on the first Monday or Tuesday of each month. The results were transmitted to the facility from the laboratory on Wednesday or Thursday of the same week. She said disinfection of the water system was "sporadic." She communicated with the biomedical technician via text messaging and was not aware of his disinfecting schedule.

In an interview on 8/19/16 at 8:30 a.m., the biomedical technician said his job responsibilities included disinfecting the water system and he did this each month, but not at the same time each month.

The facility failed to use recommended standards to protect patients from bacterial exposure.

Note: The facility was notified of an Immediate Jeopardy on 8/19/16 at 9:30 a.m. The facility

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V 254	Continued From page 13 submitted a Plan of Correction on 8/19/16 at 1:00 p.m. which stated water and dialysate samples would be collected, for CC and LAL verification, on the first Friday of each month followed by water system disinfection on the first Sunday of each month. The plan stated the corrective action would be implemented on 8/19/16. The plan's implementation was verified by signatures of understanding by the Administrator, Medical Director, and the biomedical technician. On-site verification of the plan's implementation was completed on 8/19/16 at 1:00 p.m. and the Immediate Jeopardy was removed.	V 254	See page 3 of 20	
V 543	494.90(a)(1) POC-MANAGE VOLUME STATUS 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 manage the patient's volume status; This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the facility failed to ensure prescribed EDW was attained for 2 of 3 ICHD patients (Patients #2 and #3) whose treatment sheets were reviewed. This failure resulted in patients leaving the facility at risk of complications from fluid overload. The findings include: 1. Patient #2 was an 81 year old male who had been dialyzing at the facility since 11/5/14. His EDW, prescribed on 7/29/16, was 121 kg. Nine treatment sheets from 7/29/16 - 8/17/16 were reviewed. Patient #1 did not attain his prescribed dry weight during nine of nine treatments reviewed as follows:	V 543	Policy for EDW has been developed (see Exhibit H) and includes when to notify the Medical Director for potential new orders. Staff has also been educated on the importance of trying to get patient to ordered dry weight and notifying the nurse prior to treatment end to determine if additional treatment time needs to be offered to patient under the direction of the medical director.	*09/08/16*

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V 543	Continued From page 14	V 543	See page 14 of 20	

Prescribed Estimated Dry Weight
7/29/16 121 kg

Post Treatment weight
7/29/16 - 122 kg
8/1/16 - 123.5 kg
8/3/16 - 123 kg
8/5/16 - 123 kg
8/8/16 - 123 kg
8/10/16 - 125.5 kg
8/12/16 - 124.5 kg
8/15/16 - 124 kg
8/17/16 - 123 kg

There was no documentation Patient #2 was offered extra dialysis time to remove excess fluid.

Additionally, Patient #2's care plan, dated 7/25/16, stated "Follow dry weight monitoring protocol."

2. Patient #3 was a 70 year old female who had dialyzed at the facility since 10/28/13. Her EDW was prescribed at 62 kg. Eleven treatment sheets from 7/22/16 - 8/17/16 were reviewed. Patient #3 did not attain her prescribed dry weight during five of eleven treatments reviewed as follows:

Prescribed estimated Dry Weight
7/22/16 121 kg

Post treatment Weight

7/22/16 - 63.5 kg
7/25/16 - 63.50 kg
7/27/16 - 63.5 kg
8/1/16 - 66.5 kg
8/12/16 - 63 kg

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V 543	Continued From page 15 There was no documentation Patient #3 was offered extra dialysis time to remove excess fluid. Patient #3's care plan, dated 7/25/16, stated "Follow dry weight monitoring protocol." In an interview on 8/18/16 at 5:00 p.m., the Administrator confirmed Patient #1's and Patient #3's post weight variances from their prescribed EDWs, and acknowledged the directions on Patient #2's and Patient #3's care plans. However, she said she was not aware of a dry weight protocol to guide staff in the management of patients' dry weights. A review of the Policy and Procedure Manual showed no document providing direction for the management of patients' EDWs. The facility failed to manage volume status for Patients #1 and #3.	V 543	See page 14 of 20	
V 710	494.150 CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR This CONDITION is not met as evidenced by: Based on record review and staff interview it was determined the facility failed to ensure patient care policies and procedures were developed and implemented. This failure put patients at risk of inadequate and unsafe care. The findings include: 1. Refer to V714 as it relates to the facility's failure to ensure the Medical Director participated in the development of patient care policies and procedures that were adequate, accurate and	V 710	See page 17 of 20	

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V 710	Continued From page 16 current.	V 710		
V 714	494.150(c)(1) MD RESP-DEVELOP, REVIEW & APPROVE P&P	V 714		

The medical director must-
(1) Participate in the development, periodic review and approval of a "patient care policies and procedures manual" for the facility;

This STANDARD is not met as evidenced by:
Based on policy review and staff interview, it was determined the Medical Director failed to participate in the development of policies reflecting current practice at the facility. This failure placed patients safety at risk through inconsistent nursing practice and sub-standard care. The findings include:

1. Review of the facility's Policy and Procedure Manual showed there were no documents related to water system maintenance, patient volume status, or administration of Hepatitis B vaccination.

In an interview on 8/18/16 at 5:00 p.m., the Administrator said there was no facility policy addressing maintenance of the facility's water system or action to be taken in the event of positive bacterial cultures.

In the same interview the Administrator said there was no facility policy addressing action to be taken by staff if patients did not attain their prescribed EDW.

In the same interview the Administrator said there was no facility policy directing staff as to the

09/08/16

An annual review of Bear Lake Dialysis's Policy and Procedure Manual will be done by the medical director and documented review will be placed in the front of the Policy and Procedure Manuals. Policies that need to be updated or new policies that need to be written will be discussed during the Dialysis Governing Board meeting with the Facility Administrator, Medical Director and Hospital Administrator. Policies for water system maintenance (see Exhibit D), patient volume status (see Exhibit H) and Hepatitis B Vaccine (see Exhibit A) have been written and reviewed by this board.

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V 714	Continued From page 17 timeliness of initiating Hepatitis B vaccinations. The Administrator said she reviewed the facility's Policy and Procedure Manual periodically and brought specific policies and procedures to the attention of the Medical Director if she felt a change or update was needed, but she was not sure the Medical Director had periodically reviewed all policies and procedures. In an interview on 8/19/16 at 11:00 a.m., the Medical Director said he knew full policies and procedures had been developed at the time the facility was initially certified in June, 2006 and he assumed they were still present and active. The facility failed to ensure the Medical Director developed policies and procedures that reflected current practice and addressed all areas of patient care.	V 714	See page 17 of 20	
V 750	494.180 CFC-GOVERNANCE This CONDITION is not met as evidenced by: Based on record review and staff interview it was determined the facility failed to ensure a functioning governing body was present and responsible for the facility's operation. This failure put patients at risk of inadequate care due to the lack of demonstrated responsibility for the operation of the facility. The findings include: 1. On 8/16/16 governing body meeting minutes were requested for review. The Administrator said there were no governing body meeting minutes to review. She said since September 2014, when she assumed the position of Administrator at the facility, no governing body	V 750	A functioning Dialysis Governing Board was developed and first meeting was held 09/02/2016 (see Exhibit I), with board meeting once a month from here on out. This board will consist of the Medial Director, currently Dr Clark, the current Hospital Administrator Rod Jacobson or his assistant Leslie Crane CFO, and the current Dialysis Facility Administrator Megan Green. During these meetings policy and procedures will be reviewed, grievances will be addressed, any other unit concerns will be addressed and solutions will be discussed.	09/08/16

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V 750	Continued From page 18 meeting had been held. She said she was not sure who composed the governing body. 2. Refer to V751 as it relates to the facility's failure to ensure the governing body adopted and enforced rules and regulations relative to the health care and safety of patients including, but not limited to, the safe operation of the facility's water system, the timely administration of Hepatitis B vaccinations, and the management of patients' volume status.	V 750	See page 18 of 20	
V 751	494.180 GOV-ID GOV BODY W/FULL AUTHORITY/RESPONS The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients. to the protection of the patients ' personal and property rights, and to the general operation of the facility. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the governing body failed to ensure policies and procedures were adopted and enforced to protect the health and safety of patients. This failure impacted all patients dialyzing at the facility (Patients #1 - #6), putting them at risk of infection and inadequate care. The findings include: 1. Review of the facility's Policy and Procedure Manual showed there were no documents related to the safe operation of the water system, the	V 751	See page 18 of 20	

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V 751	Continued From page 19	V 751	See page 18 of 20	

management of patient volume status, or administration of Hepatitis B vaccination.

In an interview on 8/18/16 at 5:00 p.m., the Administrator said there was no facility policy addressing the safe operation of the facility's water system or action to be taken in the event of positive bacterial cultures.

In the same interview the Administrator said there was no facility policy addressing action to be taken by staff if patients did not attain their prescribed EDW.

In the same interview the Administrator said there was no facility policy directing staff as to the timeliness of initiating Hepatitis B vaccinations.

The Administrator said she reviewed the facility's Policy and Procedure Manual periodically and brought specific policies and procedures to the attention of the Medical Director if she felt a change or update was needed, but no governing body meetings had been held to adopt additional policies as needed.

In an interview on 8/19/16 at 11:00 a.m., the Medical Director said he knew full policies and procedures had been developed at the time the facility was initially certified in June, 2006 and he assumed they were still present and active. He was not aware of any governing body activities related to policies and procedures.

The facility failed to ensure a governing body provided oversight of policy and procedure adoption and enforcement.