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DEPARTMENT OF DISABILITIES, AGING AND INDEPENDENT LIVING

Division of Licensing and Protection  
103 South Main Street, Ladd Hall  
Waterbury, VT 05671-2306  
<http://www.dail.vermont.gov>  
Voice/TTY (802) 871-3317  
To Report Adult Abuse: (800) 564-1612  
Fax (802) 871-3318

September 10, 2013

Joy Drive Renal Dialysis Unit  
35 Joy Road  
South Burlington, VT 05403

Greetings:

Enclosed is a copy of your acceptable plans of correction for the survey conducted on **August 7, 2013**. Please post this document in a prominent place in your facility.

We may follow-up to verify that substantial compliance has been achieved and maintained. If we find that your facility has failed to achieve or maintain substantial compliance, remedies may be imposed.

Sincerely,



Pamela M. Cota, RN  
Licensing Chief

PC:jl

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>473503</b>	<input checked="" type="checkbox"/> MULTIPLE CONSTRUCTION A BLDG: _____ B WING: _____	(X3) DATE SURVEY COMPLETED  08/07/2013
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NAME OF PROVIDER OR SUPPLIER  <b>JOY DRIVE RENAL DIALYSIS UNIT</b>	STREET ADDRESS, CITY, STATE ZIP CODE <b>35 JOY ROAD</b> <b>SOUTH BURLINGTON, VT 05403</b>
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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 000	INITIAL COMMENTS	V 000		
V 594	<p>494.100(c)(1)(v) H-PRECONFIG HD SYS-TEST H2O/DIALY PER DFU/FDA</p> <p>Services include, but are not limited to, the following: testing of the water and dialysate system in accordance with-</p> <p>(A) The recommendations specified in the manufacturers' instructions; and</p> <p>(B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the ESRD home hemodialysis program failed to assure testing of product water by patients for chemical analysis was conducted monthly for 1 of 17 applicable patients. (Patient # 9) Findings include:</p> <p>Per record review, Patient #9 began home hemodialysis on 3/30/12. At the time of initiation of home hemodialysis source water requirements were tested and met AAMI (American Association</p>	V 594	<p>SEE ATTACHED PLAN OF ACTION</p> <p>POC accepted B. Haun / Francis Hill RA RUSA RBA 9/19/13</p>	9/13/13

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE  <i>Carol M. ...</i>	TITLE  DIRECTOR	(X6) DATE  8/30/12
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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 594	Continued From page 1 of Medical Instruments) standards. However, as an ongoing requirement to ensure the safety of the product water used during the process of home hemodialysis, patients are instructed by the home hemodialysis nurses to perform monthly testing of product water for chemical analysis. Per record review on 8/7/13 at 11:00 PM, although there was evidence specific training instructions were provided to Patient #9 to comply with Monthly testing, there was no evidence the testing of the product water for chemical analysis had been conducted by Patient #9 for 17 months. Although the home hemodialysis program utilizes logs containing monthly water testing results for the present patient census of 17 participants of the home hemodialysis program, Patient #9 was not identified to be missing lab results for required water testing until it was brought to staffs attention by the surveyor. Upon further investigation and interview of Patient #9 on 8/7/13 by the home hemodialysis nurse confirmed the patient has not been compliant with testing since the beginning of his/her home hemodialysis treatments. Per interview on 8/7/13 at 12:15 PM the Dialysis Nurse Manager confirmed the deficient practice, noting the present staff review process lacked the ability to identify noncompliance with ongoing water testing by each individual patient receiving treatment through the home hemodialysis program. 494.100(c)(1)(v) H-MEET RD52:2004	V 594	SEE ATTACHED PLAN OF CORRECTION  C.M.H.	9/13/13
V 595	The facility must meet testing and other requirements of ANSI/AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.	V 595	SEE ATTACHED PLAN OF CORRECTION	9/13/13

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 ICARE & MEDICAID SERVICES

PRINTED: 08/20/2013  
 FORM APPROVED  
 OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  473503	(X2) WING A BLDG _____  B WING _____	CONSTRUCTION	(X3) DATE SURVEY COMPLETED  08/07/2013
NAME OF PROVIDER OR SUPPLIER  JOY DRIVE RENAL DIALYSIS UNIT			STREET ADDRESS, CITY, STATE, ZIP CDDE 36 JOY ROAD SOUTH BURLINGTON, VT 05403		
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V 595	Continued From page 2  This STANDARD is not met as evidenced by: Based on interview and record review, the ESRD home hemodialysis program failed to assure testing of water and dialysate for bacteriological and endotoxins was conducted for 1 of 17 applicable patients. (Patient #9) Findings include:  Per record review, Patient #9 began home hemodialysis on 3/30/12. At the time of initiation of home dialysis water testing was conducted and met AAMI standards. However, as an ongoing requirement to ensure the safety of the water and dialysate used during the process of home hemodialysis, patients are instructed by the home hemodialysis nurses to perform monthly testing for the quality of the water and dialysate. Sampling is for the purpose of detecting bacterial and endotoxin content. Per record review on 8/7/13 at 11:00 PM, although there was evidence specific training instructions was provided to Patient #9 for conducting the monthly microbiological testing, there was no evidence the testing was actually performed by Patient #9 for 17 months. Although the home hemodialysis program utilizes logs containing monthly water testing results for the present patient census of 17 participants of the home hemodialysis program, Patient #9 was not identified to be missing lab results for required water and dialysate testing until it was brought to staffs attention by the surveyor. Upon further investigation and interview of Patient #9 on 8/7/13 by the home hemodialysis nurse confirmed the patient has not been compliant with testing since the beginning of his/her home hemodialysis treatments. Per interview on 8/7/13 at 12:15 PM the Dialysis Nurse Manager confirmed the deficient practice, noting the	V 595	SEE ATTACHED PLAN OF CORRECTION  C. Hus	9/13/13	

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NAME OF PROVIDER OR SUPPLIER  <b>JOY DRIVE RENAL DIALYSIS UNIT</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>35 JOY ROAD SOUTH BURLINGTON, VT 05403</b>			
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V 595	Continued From page 3 process utilized by the home hemodialysis program lacked the ability to identify noncompliance with ongoing water testing by each individual patient receiving treatment through the home hemodialysis program. The Dialysis Nurse Manager also noted the Chief Technician for the providers entire dialysis program reviews the microbiological test results on a monthly basis. However, the Chief Technician had not been made aware of the total census for patients on service with the home hemodialysis program and was unaware 1 of the 17 home hemodialysis patient results had been consistently missing.					
V 628	494.110(a)(2) <b>QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS</b>  The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves.  This STANDARD is not met as evidenced by: Based on interview and record review, the ESRD home hemodialysis program failed to develop a system that would effectively identify and track patient performance and outcomes of water and dialysate testing. Findings include:  During the course of record review and staff interview, it was determined the home hemodialysis program provided substantial training and preparation of patients and/or their	<del>494.110(a)(2)</del>  V 595	SEE ATTACHED Plan of CORRECTION  C. Muz	9/13/13		

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V 628	<p>Continued From page 4</p> <p>safe and effective home hemodialysis treatment was performed. Training included the monthly testing of product water for chemical analysis and water and dialysate for endotoxins and bacteria. The patients are instructed to do water and dialysate sampling and directed how to submit the samples for testing. The present monitoring system utilized by patients and home program staff which captures results of testing of water and dialysate quality failed to identify 1 of 17 patients in the home hemodialysis program had not been compliant with water testing. Per review of documentation identified by home hemodialysis nursing staff as the logs used to track results of monthly water and dialysate testing failed to include 1 of the 17 patients presently on the home hemodialysis program. Per record review, Patient #9 began home hemodialysis on 3/30/12. At the time of initiation of home dialysis source water requirements were tested and met AAMI (American Association of Medical Instruments) standards. Over the past 17 months since the initial testing, Patient #9 failed to conduct the required monthly testing of water and dialysate and the present system for tracking the outcomes of the testing failed to identify this deficient practice.</p> <p>Per interview on 8/7/13 at 12:15 PM the Dialysis Nurse Manager confirmed the present process for all water and dialysate cultures and endotoxin levels are, presently reviewed by the Chief Technician for the entire ESRD programs. The Chief Technician will bring to the attention of a dialysis unit, Medical Director and/or home hemodialysis staff if cultures and testing do not meet AMMI guidelines: However, the present process does not include the number of patients on service with the home hemodialysis program</p>	V 628	<p>SEE ATTACHED PLAN OF CORRECTION C.M.W.</p>	9/13/13
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		B. WING		

NAME OF PROVIDER OR SUPPLIER <b>JOY DRIVE RENAL DIALYSIS UNIT</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>SOUTH BURLINGTON, VT 05403</b>
<b>3 5 J O Y R O A D</b>	

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V 628	Continued From page 5 and therefore the Chief Technician was not aware 1 of the 17 monthly patient tests had been consistently missing.	V 628	<p>SEE ATTACHED Plan of Correction C. H. W.</p>	9/13/13

## PLAN OF CORRECTION

### *V 000 INITIAL COMMENTS*

*An unannounced on-site recertification survey was completed on 8/5/13 through 8/7/13 to determine compliance with 42 Code of Federal Regulations, Part 405, Subpart U, Conditions for Coverage for End Stage Renal Disease Services. The following regulatory violations were identified.*

### *V 594 494.100(c)(1)(v) H-PRECONFIG HD SYS-TEST H2O/DIALY PER DFU/FDA*

*Services include, but are not limited to, the following; testing of the water and dialysate system in accordance with The recommendations specified in the manufacturers' instructions; and The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine . testing) water and dialysate.*

*This STANDARD is not met as evidenced by: Based on interview and record review, the ESRD home hemodialysis program failed to assure testing of product water by patients for chemical analysis was conducted monthly for 1 of 17 applicable patients. (Patient # 9) Findings include:*

*Per record review, Patient #9 began home hemodialysis on 3/30/12. At the time of initiation of home hemodialysis source water requirements were tested and met AAMI (American Association of Medical Instruments) standards. However, as an ongoing requirement to ensure the safety of the product water used during the process of home hemodialysis, patients are instructed by the home hemodialysis nurses to perform monthly testing of product water for chemical analysis. Per record review on 8/7/13 at 11:00 PM, although there was evidence specific training instructions were provided to Patient #9 to comply with Monthly testing, there was no evidence the testing of the product water for chemical analysis had been conducted by Patient #9 for 17 months. Although the home hemodialysis program utilizes logs containing monthly water testing results for the present patient census of 17 participants of the home hemodialysis program, Patient #9 was not identified to be missing lab results for required water testing until it was brought to staffs attention by the surveyor. Upon further investigation and interview of Patient #9 on 8/7/13 by the home hemodialysis nurse confirmed the patient has not been compliant with testing since the beginning of his/her home hemodialysis treatments. Per interview on 8/7/13 at 12:15 PM the Dialysis Nurse Manager confirmed the deficient practice, noting the present staff review process lacked the ability to identify noncompliance with ongoing water testing by each individual patient receiving treatment through the home hemodialysis program.*

### ACTION PLAN/PERFORMANCE IMPROVEMENT PLAN

In order to assure testing in accordance with the ANSI AAMI RD52:2004 standards the following system updates were added effective 8/24/2013 under the direction of the Nurse manager to support compliance for ongoing water testing: A water testing prompt was added to the Daily Patient Log utilized by each Home Dialysis patient to serve as a reminder for the patient to submit the appropriate samples. This log is reviewed by the staff when the logs are submitted and/or at the monthly patient clinic visit with each patient. A prompt for the RN to verify and document appropriate water testing was submitted, reviewed and verified was added to the nursing monthly clinic note.

The Home Hemodialysis New Start Checklist will be updated by 9/6/13, by the Nurse Manager to include notification of new patients to the System Tech water quality assurance tracking inventory. This checklist is utilized for each new patient to assure all necessary items are addressed. This will ensure that any new patient will be included in the total census and quality assurance checking.

The Fletcher Allen Policies entitled: Testing Dialysate for LALs and Microbiologic Quality NxStage: System One with PureFlow SL and Testing for Product Water Quality (Chemical Analysis) for NxStage System One with PureFlow SL will be updated by the Nurse Manager to include system updates and performance monitoring by 9/6/13.

Each Home Hemodialysis patient was reeducated by the Home Hemodialysis RN's on the required water testing frequency and the addition water testing prompt on the Patient Daily Log during the month of August 2013.

Home Hemodialysis RN staff and Patient Care Technicians will be educated by the Nurse Manager and Renal Technician Manager at staff meetings on the updated Fletcher Allen Policies entitled: Testing Dialysate for LALs and Microbiologic Quality NxStage: System One with Pure Flow SL and Testing for Product Water Quality (Chemical Analysis) for NxStage System One with PureFlow SL. This education will be completed by 9/13/13.

Verification that every patient on the census has had the appropriate water testing and results are within the required specifications will be monitored monthly by the Renal Technician. This performance data will be compiled by the Renal System Technician and sent to the Renal Technician Manager for final review. The Renal Technician Manager will communicate the results to the Nursing Leadership. The Nurse Manager will review monthly the Home Hemodialysis Clinic Note to ensure completeness of appropriate water testing documentation and appropriate review. Performance feedback will be provided as appropriate.

Compliance with required Home Hemodialysis water testing will be added as a quality measure. This measure will be reviewed monthly by the Home Hemodialysis Medical Director, Nurse Manager and Home Hemodialysis Program RN's at the monthly quality assurance meetings.

*V 595 494.100(c)(1)(v) H-MEET RD52:2004*

*The facility must meet testing and other requirements of ANSI/AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits*

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Compliance with required Home Hemodialysis water testing will be added as a quality measure. This measure will be reviewed monthly by the Home Hemodialysis Medical Director, Nurse Manager and Home Hemodialysis Program RN's at the monthly quality assurance meetings.

*V 628 494.110(a)(2)QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS*

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*process does not include the number of patients on service with the home hemodialysis program and therefore the Chief Technician was not aware 1 of the 17 monthly patient tests had been consistently missing*

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The Nurse Manager will review monthly the Home Hemodialysis Clinic Note to ensure completeness of appropriate water testing documentation and appropriate review. Performance feedback will be provided as appropriate.

Compliance with required Home Hemodialysis water testing will be added as a quality measure. This measure will be reviewed monthly by the Home Hemodialysis Medical Director, Nurse Manager and Home Hemodialysis Program RN's at the monthly quality assurance meetings.