

Division of Licensing and Protection

HC 2 South, 280 State Drive

Waterbury, VT 05671-2060

<http://www.dail.vermont.gov>

Survey and Certification Voice/TTY (802) 241-0480

Survey and Certification Fax (802) 241-0343

Survey and Certification Reporting Line: (888) 700-5330

To Report Adult Abuse: (800) 564-1612

July 26, 2016

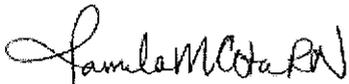
Sandra Hicks, Clinical Manager
Fresenius Medical Care St Johnsbury
1080 Hospital Drive
Saint Johnsbury, VT 05819

Dear Ms. Hicks:

Enclosed is a copy of your acceptable plans of correction for the survey conducted on June 28, 2016. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 08/29/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 472501	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/28/2016
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE ST JOHNSBURY			STREET ADDRESS, CITY, STATE, ZIP CODE 1080 HOSPITAL DRIVE SAINT JOHNSBURY, VT 05819	
(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 An unannounced on-site recertification survey was conducted by the Division of Licensing and Protection from 6/27/16 to 6/28/16 to determine compliance with 42 Code of Federal Regulations Part 405, Subpart U Conditions for Coverage for End Stage Renal Disease Facilities. The following regulatory violations were identified:	V 000	Upon the conclusion and exit interview from the June 28, 2016 Vermont Department of Aging and Independent Living, Division of Licensing and Protection survey, the operation team took immediate action by: • A staff meeting was held on June 29, 2016 to review a summary of the exit interview findings. • On July 1, 2016 the findings from the exit interview were reviewed by the Governing Body with discussion on immediate action steps that need to be taken. • On July 12, 2016 the Statement of Deficiency was reviewed by the Governing Body and the following Plan of Correction was developed. <i>V000 POC accepted J. Cummins RUMS 7/29/16</i>	
V 113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. This STANDARD is not met as evidenced by: Based upon observation, staff interviews, and record reviews 4 staff members failed to adhere to the facility's policy and procedure regarding appropriate use of gloves and hand hygiene during and between the provision of patient care and touching dialysis equipment including the Chairside charting device for 6 applicable patients. (Staff #1, #2, #3, #4, #6 & #13). Findings include: 1. During observation of the initiation of dialysis with central venous catheter for Patient #6 on 6/27/16, RN #1 sanitized his/her hands, touched the screen of the Chairside charting device with bare hands, then donned clean gloves without sanitizing, and then touched the dialysis machine. On 6/27/16 at 12:22 PM, RN #1 confirmed that s/he touched the screen of the Chairside charting device with bare hands, then donned clean	V 113	In response to the citation received during the June 28th survey, the Clinical Manager conducted a mandatory staff meeting on June 29, 2016 to reinforce the following: • Hand hygiene is imperative after contact with the chair side computer and before contact with the patient. • Hands must be sanitized and/or washed with soap and water after removing gloves and before donning clean gloves, before and after direct contact of patients, and after contact with inanimate objects near the patient. • One must remove gloves, sanitize hands and don clean gloves prior to transporting the blood specimen tubes and coming into contact with the refrigerator. An in-service was held for all DPC (direct patient care) staff on 7/13/2016 by the area Education Coordinator to reeducate staff on the following FMC Policies & Procedures: • FMS-CS-IC-II-155-090A Hand Hygiene Policy • FMS-CS-IC-II-115-090C Hand Hygiene Procedure • FMS-CS-IC-II-155-110A Cleaning and Disinfection Policy With special emphasis on wearing disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station, and removing gloves and sanitizing and/or washing hands between each patient or station. <i>V113 POC accepted J. Cummins RUMS 7/29/16</i>	7/29/2016
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>Stichler RN</i>		TITLE <i>Clinical Manager</i>		(X6) DATE <i>7/29/16</i>

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 113	Continued From page 1 gloves without sanitizing, and then touched the dialysis machine. Per FMS Clinical Services Policy IC-II-155-090A Hand Hygiene 20-MAR-2013 and confirmed with the Clinical Education Coordinator on 6/27/16 at 4:32 PM, hands must be decontaminated using an alcohol based hand rub or by washing hands with soap and water after contact with inanimate objects near the patient. Per FMS Clinical Services policy CS-IC-II-155-110 A Cleaning and Disinfection 28-Jan-2015 States: "Hand hygiene is imperative after contact with the chair side computer devices and before contact with the patient." 2. Per observation on 6/27/16 at 10:30 AM, Staff Member #4 was observed accessing Patient #5's AV Fistula, drawing a blood sample and initiating dialysis. Without removing gloves, which were potentially contaminated with blood, dialysate or other infectious substances from the initiation of dialysis, Staff Member #4 was observed carrying the blood sample tube from the dialysis station to the lab specimen refrigerator. With a soiled glove hand, Staff Member #4 made contact with the outside of the refrigerator while opening and placing the blood sample tube inside the refrigerator. Per interview on 2:45 PM on 6/27/16, Staff Member #4 confirmed s/he failed to remove gloves, sanitize hands and don clean gloves prior to transporting the blood specimen tube and coming in contact with the refrigerator, acknowledging the opportunity for cross contamination. Observations made on 6/27/16 noted multiple staff accessing this refrigerator through out the day of dialysis treatment. 3. Per observation, on the morning of 6/27/16, Staff Member #3, opened the door of the	V 113	Compliance will be monitored using the Plan of Correction tool daily for 2 weeks, alternating shifts by the Clinical manager or designee. If compliance is observed, the QAI Infection Audit Tool will be used by the CM following the QAI process. Issues of non-compliance will result in reeducation and progressive discipline. The CM will present the education and results of the audits at the monthly QAI committee meeting and Governing Body meetings. The CM will be responsible. The QAI Committee will have oversight. In-service and audit records are available at the facility for review. <i>V113 POC accepted J. Cumney RUMS 7/26/16</i>		

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V 113	<p>Continued From page 2</p> <p>specimen refrigerator with the same contaminated gloved hand that was used to draw blood and complete a dressing change on Patient #2. The Staff Member confirmed, during interview on the afternoon of 6/27/16, that s/he had not removed his/her gloves or sanitized hands after withdrawing blood from a catheter line and then applying a dressing to the CVC (central venous catheter) insertion site of Patient #2. S/he confirmed s/he had used the same contaminated gloved hand to open the door of the specimen refrigerator.</p> <p>4. Per observation on 6/27/16 at 11:10 AM Staff Member #3 was observed entering Station #12 in response to an infusion pump alarm. The staff member manipulated IV (intravenous) tubing connected to an infusion pump and also was in contact with the access site for Patient # 13 who was receiving an antibiotic infusion. Upon leaving Station #12, Staff Member #3 failed to sanitize hands and/or wash hands after removing contaminated gloves and donning clean gloves prior to manipulating and cleaning equipment in Station #4.</p> <p>5. Per observation on 6/27/16 at 11:00 AM, Staff Member # 2 was observed cleaning Station #11. During the cleaning process a patient's dialysis machine alarm sounded in Station #13 and Staff Member #2 was asked to respond to the alarm. However, prior to entering Station #13, Staff Member #2 failed to sanitize hands after removing contaminated gloves. Upon entering Station #13 Staff Member #2 applied one glove but with an ungloved hand touched the dialysis machine. Per interview on 6/27/16 at 2:55 PM, Staff Member # 2 and facility educator were informed of the observations. Staff member #2</p>	V 113	<p><i>V113 POC accepted</i> <i>J. Cummins RN MS.</i> <i>7/26/16</i></p>	
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V 113 Continued From page 3
stated s/he was not aware of the breach in infection control practice.

Per FMS- CS-IC-II-155-090A Hand Hygiene Policy (last revised 20-MAR-2013) states: " Purpose of this policy is to prevent transmission of pathogenic microorganisms to patients and staff through cross contamination." The policy further states: " Hands will be decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water. When before and after direct contact with patients...before performing any invasive procedure such as vascular access cannulation or administration of parental medications...immediately after removing gloves...after contact with inanimate objects near the patient..."

V 113
*V113 POC accepted
J. Cummins RN MS
7/26/16*

V 114 494.30(a)(1)(i) IC-SINKS AVAILABLE

A sufficient number of sinks with warm water and soap should be available to facilitate hand washing.

This STANDARD is not met as evidenced by: Based upon patient and staff interviews the facility failed to ensure that 1 applicable patient (Patient #5) wash the access site with soap and water at a designated sink, prior to treatment. Findings include:

1. During interview on 06/27/16 at 10:35 AM Patient #5 stated that for infection control practices that [she/he] washed the access site, at home prior to coming to treatment. The Patient acknowledged that although the access site was not washed with soap and water at a designated

V 114 In response to the citation received during the June 28th survey, the Clinical Manager conducted a mandatory staff meeting on June 29, 2016 in relation to the following:
• All patients must wash hands and access upon entering the unit.
• If patient is unable to do so independently, please assist them.
An in-service was held for all DPC (direct patient care) staff on 7/13/2016 by the area Education Coordinator to reeducate staff on the following FMC Policies & Procedures:
• FMS-CS-IC-115-006A Assessment and Preparation of Internal Access for Needle Placement Policy
• FMS CS IC 115-006C Assessment and Preparation of Internal Access for Needle Placement Procedure
With special emphasis on Step 1: "Ask your patient to wash access area with liquid soap for one minute, rinsing well. Dry with paper towel."

V114 POC accepted
*J. Cummins RN MS
7/26/16*

7/29/2016

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V 114	Continued From page 4 sink, "{ staff} took the alcohol pad and cleaned it before treatment". In the afternoon a Dialysis Technician (DT) explained that patients are expected to wash the access site with soap and water, prior to treatment at one of the designated sinks. The DT explained that staff will sometimes help those patients who are unable to accomplish this on their own. Staff are assured this is happening. The DT further stated that if a person was to wash the access at home they would still have to wash at the facility "because you can't be sure if it (access site) got contaminated between home to here". Per interview at 2:16 PM Staff #4 stated that Patient #5 "will sometimes need our help washing the access site at the sink". Staff #4 confirmed that the patient was not assisted nor was asked if the access site was washed with soap and water at a designated sink. Per FMS-CS-IC-I-115-006C Assessment and Preparation of Internal Access for Needle Placement Procedure (effective 25-SEP-2013) states: "Step 1: Ask your patient to wash access area with liquid soap for one minute, rinsing well. Dry with clean paper towel."	V 114	Compliance will be monitored using the Plan of Correction tool daily for 2 weeks, alternating shifts by the Clinical manager or designee. If compliance is observed, the QAI Infection Audit Tool will be used by the CM following the QAI process. Issues of non-compliance will result in reeducation and progressive discipline. In addition, the patients will be given a Handout about hand and access disinfection prior to and following treatment. The DPC staff will review the handout with all patients. Education will be documented in the patient Medical Record. DPC staff will also remind patients of requirement to wash hands and access prior to initiating treatment. If continued patient noncompliance occurs, the QAI committee will review findings and recommend an action plan for each patient. The CM will present the education and results of the audits at the monthly QAI committee meeting and Governing Body meetings. The CM will be responsible. The QAI Committee will have oversight. In-service and audit records are available at the facility for review. <i>V114 POC accepted J. Cummins RUMS 7/26/16</i>	
V 121	494.30(a)(4)(i) IC-HANDLING INFECTIOUS WASTE [The facility must demonstrate that it follows standard infection control precautions by implementing-] (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the- (i) Handling, storage and disposal of potentially infectious waste;	V 121	<i>V 121 POC accepted J. Cummins RUMS 7/26/16</i>	

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V 121	Continued From page 5 This STANDARD is not met as evidenced by: Based on observation and staff interview, staff failed to maintain standard infection control precautions when disposing of potentially infectious waste during the cleaning and disinfection of dialysis stations. Findings include: Per observations of the disinfection of dialysis stations during the morning of 6/27/16 at stations #10, 11 & 12, staff failed to appropriately dispose of trash which contained potentially infectious waste used during a dialysis treatment to include soiled gloves, bandages, gauze, tape and used disinfectant wipes. Upon completion of the cleaning of the dialysis station and preparing for the next patient's treatment, staff were observed removing from the dialysis station a trash container which was lined with a plastic bag over to a larger trash receptacle. Instead of removing the plastic bag with its soiled contents into the receptacle, staff were observed disposing the contents and returning the trash container with the remaining soiled bag back to the dialysis station. The trash container was placed in close proximity to the patient's chair and was reused again during the next dialysis treatment creating a potential opportunity for cross-contamination. Per interview on 6/28/16 at 2:15 PM the dialysis unit Clinical Manager stated it was the expectation staff would dispose both the trash bag with contents into the larger trash receptacle and not return the trash container with the soiled bag to the cleaned and disinfected dialysis station.	V 121	In response to the citation received during the June 28th survey, the Clinical Manager conducted a mandatory staff meeting on June 29, 2016 to reinforce the following: - Staff will dispose both non biohazard trash bag and its contents into the larger central trash receptacle before cleaning and disinfecting the station. - No trash container will be returned to the cleaned and disinfected station with a soiled bag. An in-service was held for all DPC (direct patient care) staff on 7/13/2016 by the area Education Coordinator in which she reinforced the above. Compliance will be monitored using the Plan of Correction tool daily for 2 weeks, alternating shifts by the Clinical manager or designee. If compliance is observed, the QAI Infection Audit Tool will be used by the CM following the QAI process. Issues of non-compliance will result in reeducation and progressive discipline. The CM will present the results of the audits at the monthly QAI committee meeting and Governing Body meetings. The CM will be responsible. The QAI Committee will have oversight. In-service and audit records are available for review.	7/29/2016	
V 122	494.30(a)(4)(ii) IC-DISINFECT	V 122			

*V 121 POC accepted
J. Cummings RUMS
7/26/16*

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V 122	<p>Continued From page 6</p> <p>SURFACES/EQUIP/WRITTEN PROTOCOL</p> <p>[The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(1) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>This STANDARD is not met as evidenced by: Based on observations and interview, staff failed to consistently clean and disinfect contaminated surfaces during the cleaning and disinfecting of the dialysis station. Findings include:</p> <p>Per observations on the morning of 6/27/16 of the cleaning and disinfecting of dialysis stations, staff failed to consistently clean the stand alone Chairside charting device used between stations #9 and #10 and between stations #11 and #12. This charting device is used multiple times by both nursing and renal technicians during the initiation of dialysis, at times during the treatment session and as needed to record patient's clinical information. Per FMS-CS-IC-II-155-110 A Cleaning and Disinfection Policy effective 28-Jan-2015 states: "The area that includes the Chairside charting device is considered a clean area and not part of the patient's station....Hand hygiene is imperative after contact with the Chairside computer devices and before contact with the patient. If equipment becomes contaminated, follow cleaning and disinfecting procedures."</p> <p>Per interview on 6/28/16 at 2:00 PM, the dialysis</p>	V 122	<p>- In response to the citation received during the June 28th survey, the Clinical Manager conducted a mandatory staff meeting on June 29, 2016 to reinforce the following:</p> <ul style="list-style-type: none"> We must consistently clean and disinfect contaminated surfaces during the cleaning and disinfecting of the dialysis station including chairside <p>An in-service was held for all DPC (direct patient care) staff on 7/13/2016 by the area Education Coordinator to reeducate staff on the following FMC Policy & Procedure:</p> <ul style="list-style-type: none"> FMS-CS-IC-II-155-110A Cleaning and Disinfection <p>With special emphasis on including chairside during the cleaning and disinfection of the dialysis station at the time of changeover.</p> <p>In addition to this, new dialysis machines have been ordered and are expected to arrive 3rd quarter 2016, that have built in data entry stations, which will eliminate the chairside.</p> <p>Compliance will be monitored using the Plan of Correction tool daily for 2 weeks, alternating shifts by the Clinical manager or designee. If compliance is observed, the QAI Infection Audit Tool will be used by the CM following the QAI process. Issues of non-compliance will result in reeducation and progressive discipline.</p> <p>The CM will present the education and results of the audits at the monthly QAI committee meeting and Governing Body meetings. The CM will be responsible. The QAI Committee will have oversight. In-service and audit records are available in the facility for review.</p> <p><i>V122 POC accepted J. Cummings RN MS 7/26/16</i></p>	7/29/2016

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V 122	Continued From page 7 unit Clinical Manager stated it is his/her expectation that staff would be wiping down the Chairside charting device during the cleaning of each dialysis station using the 1:100 bleach wipes. However, although the staff were observed in various stages of cleaning and disinfection of dialysis stations they failed to include the Chairside charting devices when cleaning at the time of changeover between patients in an effort to prevent opportunity for cross-contamination.	V 122	<i>V 122 POC accepted J. Cummings RUMS 7/26/16</i>		
V 147	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters. II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients. VI. Catheter and catheter-site care	V 147	In response to the citation received during the June 28th survey, the Clinical Manager conducted a mandatory staff meeting on June 29, 2016 to reinforce the following: The RNs were reminded that they must adhere to appropriate infection control guidelines and practices during the provision of care to CVC (central venous catheter) sites. An in-service was held for all RNs (registered nurses) on 7/13/2016 by the area Education Coordinator to reeducate staff on the following FMC Policies & Procedures: • FMS CS IC II-105-032A Changing the Catheter Dressing Policy • FMS-CS-4C-II-105-032C: Changing the Catheter Dressing Procedure • FMS CS-4C-II-105-002A Initiation of Treatment Using a Central Venous Catheter Policy • FMS CS IC II-105-002C Initiation of Treatment Using a Central Venous Catheter Procedure • FMS-CS-4C-II-105-028A Termination of Treatment Using a Central Venous Catheter Policy • FMS-CS-4C-II-105-028C Termination of Treatment Using a Central Venous Catheter Procedure	7/29/2016	
			<i>V 147 POC accepted J. Cummings RUMS 7/26/16</i>		

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V 147	<p>Continued From page 8</p> <p>B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>This STANDARD is not met as evidenced by: Based on observations, staff interviews and record review, the facility failed to assure that all staff consistently adhered to appropriate infection control guidelines and practices during the provision of care to CVC (Central Venous Catheter) sites for 1 of 2 patients. (Patient #2). Finding includes:</p> <p>1. During observation of a CVC dressing change for Patient #2, at 11:30 AM on the morning of 6/27/16, Staff Member #3 failed to maintain a clean field and failed to change gloves and/or sanitize hands between dirty and clean procedures. A clean field was established, prior to the initiation of a dressing change, to hold the supplies needed. After removing the old dressing Staff Member #3 removed gloves, performed hand sanitization and donned clean gloves for use in cleansing the area around the CVC insertion site with a chloraprep swab. After cleansing the area the staff member placed the contaminated chloraprep swab on the clean field containing the clean supplies, which included the new packaged sterile dressing. While waiting for the area to dry, and before placing a new dressing, the staff member withdrew blood from one of the catheter lines and placed the blood filled test tube on the clean field with the clean dressing. In addition, the staff member then used the same contaminated gloves to place the clean</p>	V 147	<p>Including demonstration of procedure by the Educator, with return demonstration by the RN's. A CVC Annual Skills Validation & Attestation was signed off upon completion and placed in employee files.</p> <p>Compliance will be monitored using the Plan of Correction tool daily for 2 weeks, alternating shifts by the Clinical manager or designee. If compliance is observed, the QAI Infection Audit Tool will be used by the CM following the QAI process. Issues of non-compliance will result in reeducation and progressive discipline.</p> <p>The CM will present the results of the audits at the monthly QAI committee meeting and Governing Body meetings. The CM will be responsible. The QAI Committee will have oversight.</p> <p>In-service and audit records are available for review.</p> <p><i>V147 PO Accepted J. Cumming RN MS 7/26/16</i></p>	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 472501	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/28/2016
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dressing on the CVC insertion site.

During interview, on the afternoon of 6/27/16, the Nurse Manager agreed that contaminated supplies, including the chloraprep swab, should be disposed of and not placed on a clean field with clean supplies. S/he also agreed that Staff Member #3 should have changed gloves and sanitized hands after withdrawing blood and prior to placing the clean dressing.

V 147

V147 POC accepted
J. Cummings RUMS
7/26/16