

Division of Licensing and Protection
103 South Main Street
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 22, 2015

Ms. Isabelle Sargeant, Administrator
Fletcher Allen Health Care - S
160 Allen St
Rutland, VT 05701

Dear Ms. Sargeant:

Enclosed is a copy of your acceptable plans of correction for the survey conducted on **August 5, 2015**. 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

SEP 04 2015

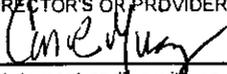
PRINTED: 08/25/2015
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 473501	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 08/05/2015
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NAME OF PROVIDER OR SUPPLIER FLETCHER ALLEN HEALTH CARE - S	STREET ADDRESS, CITY, STATE, ZIP CODE 160 ALLEN ST RUTLAND, VT 05701
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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
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V 000	INITIAL COMMENTS An unannounced on-site re-certification survey was conducted by the Division of Licensing and Protection from 8/3/15 - 8/5/15 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 000		
V 117	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients. This STANDARD is not met as evidenced by: Based on observation and staff interview, the dialysis unit failed to assure prepared packets of supplies used for initiation of fistula and CVC (central venous catheter) treatments were stored	V 117	SEE ATTACHED PLAN OF CORRECTION	9/3/15

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE Director	(X6) DATE 8/31/15
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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 117	Continued From page 1 in a clean and sanitary manner. Findings include: During a tour on 8/4/15 at 10:55 AM of locations where unused supplies and equipment is stored for dialysis treatment, a large closet in a hallway was identified by the Unit Secretary to be the main location for supply storage. Upon observation, multiple prepared supply packets prepared by staff and containing syringes, gauze, alcohol wipes and other supplies used to clean and disinfect the access sites and/or tubing in both the initiation and discontinuation of dialysis treatment were piled in open boxes and plastic containers surrounded by boxes, and other stocked items. As a result, the prepared packets remained exposed and susceptible to possible contamination. At 11:05 AM the Dialysis Site Supervisor and the Nurse Manager for Renal Services confirmed the packets should not have been stored in the hallway closet acknowledging cabinets located in front of the nurse's station are specifically designated for the safe and sanitary storage for the prepared packets to maximize the protection of the supplies from cross contamination.	V 117	<i>SEE ATTACHED PLAN OF CORRECTION</i>	<i>9/30/15</i>	
V 122	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [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-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.	V 122	<i>SEE ATTACHED PLAN OF CORRECTION</i>	<i>9/30/15</i>	

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V 122	<p>Continued From page 2</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, facility staff failed to follow standard infection control precautions by not adequately cleaning and disinfecting contaminated surfaces of two dialysis stations following discontinuation of dialysis patient treatments and prior to the arrival of the next scheduled patients. (Patient #13) Findings include:</p> <p>1) Per observation on 8/3/15 at 10:45 AM of the cleaning and disinfection of dialysis Station #9 between the first and second patient dialysis treatment sessions, Staff member #4 failed to fully recline/extend the dialysis chair to assure all surfaces were effectively wiped with disinfectant prior to the next scheduled patient was to utilize the chair during dialysis treatment.</p> <p>2) Per observation of the cleaning and disinfection of Station #2 on 8/3/15 at 3:15 PM, Staff #4 did not fully recline the dialysis chair and wipe all visible surfaces with a disinfectant after Patient #13 vacated the chair and before the next scheduled patient arrived. Staff #4 confirmed on 8/3/15 at 3:15 that she/he did not fully extend the dialysis chair and wipe all visible surfaces with a disinfectant. Surveyor brought this to Staff #4's attention and the chair was fully reclined and disinfected before the next scheduled patient arrived.</p> <p>In addition, the facility Infection Prevention Policy: Hemodialysis Out-patient and In-patient Care Sites date released July 2013 states "After each patient treatment, after patient has been discharged from the station, clean environmental surfaces at the dialysis station, including the dialysis bed or chair, countertops, and external</p>	V 122	<p>SEE ATTACHED PLAN OF CORRECTION</p>	9/30/15

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V 122	Continued From page 3 surfaces of the dialysis machine, including containers associated with the prime waste". 3) Per observation of the cleaning and disinfection of Station #2 on 8/3/15 at 3:05 PM following discontinuation of Patient #13's dialysis treatment, Staff #4 placed contaminated blood lines on the dialysis machine in such a manner that the bloodlines touched the floor in front of the machine. Staff #4 was observed walking in this area, walking away from the station, and returning to the station. Staff #4 confirmed that contaminated blood lines were touching the floor and that she/he walked in this area, walked away, and returned. The floor was disinfected after the surveyor brought it to the attention of Staff #4 and prior to arrival of the next dialysis scheduled patient.	V 122			
V 146	494.30(c)(2) IC-CATHETERS:GENERAL (2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For	V 146		SEE ATTACHED PLAN OF CORRECTIVE 9/8/2015	

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V 146	<p>Continued From page 4</p> <p>information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html</p> <p>This STANDARD is not met as evidenced by: Based upon observation, interview and record review, facility staff failed to maintain strict adherence to the organizational policy when performing hemodialysis vascular access care of a central venous catheter (CVC) during a dressing change, initiation, and discontinuation of treatment for two patients and failed to maintain an environment free from the potential for cross contamination for one patient. (Patients #3 & #5) Findings include:</p> <p>Per review the facility policy, Hemodialysis Vascular Access: Central Venous Catheter (CVC) Care and Maintenance procedure for de-accessing CVC, dated 5/14/14, states: "Prior to bloodline disconnection, the technician or RN [registered nurse] will don gown and mask, perform hand hygiene, don gloves, and place a chux under the catheter/bloodline junction." The policy also states the RN will "Scrub each extension tubing and clamp, and junction of bloodline and catheter with alcohol swabs, and hold the extensions above the chux with an alcohol swab, while placing the 4 x 3 under the extension/bloodline junction."</p> <p>1. Based upon observation of a patient with a central venous catheter (CVC) discontinuing dialysis treatment on 8/3/15 at 1:45 PM, Staff #1 failed to place a chux or other clean field under Patient #3's CVC bloodline junctions prior to</p>	V 146	<p>SEE ATTACHED PLAN OF CORRECTION</p>	9/30/15	

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V 146	Continued From page 5 cleaning the catheter extensions, tubing, clamp, and bloodline junction with alcohol swabs. In addition, after Staff #1 cleaned the extensions, tubing, clamp, and bloodline junctions s/he wrapped the extensions with a gauze pad without a clean field being present underneath. Staff #1 confirmed on 8/3/15 at 1:50 PM that she/he did not place a clean field under the CVC bloodline junctions prior to cleaning and wrapping the extensions with a gauze pad. 2. Per record review, Patient #5 was hospitalized from 7/1/15 to 7/15/15 with sepsis after developing a significant central line bloodstream infection (CLBSI). The infected CVC was removed and eventually a new hemodialysis CVC was inserted prior to discharge from the hospital and dialysis treatment was resumed at the satellite unit. Per observation of Patient #5's CVC dressing change on 8/5/15 at 11:05 AM, Staff member #10 failed to maintain strict adherence to the dialysis department infection control policy. Staff member #10 was observed removing the old CVC dressing, cleaning the CVC insertion site and catheter and applied a new dressing to the CVC site with only a 4 x3 gauze pad under the catheter extensions without the use of a chux pad, as per policy, which would have provided an additional clean field barrier prior to the initiation of the dressing change and accessing the CVC for dialysis. It was also noted Patient #5 was receiving treatment at Station #3 which is located directly beside the entrance/exit to the Satellite unit, a high traffic area. Individuals were observed passing in close proximity of Patient #5 while s/he sat in the dialysis chair during the CVC dressing change procedure. At the time of the dressing change, Staff member # 10 failed to draw the privacy curtain around Station #3 to	V 146			

*SEE
ATTACHED
PLAN OF
CORRECTION*

9/30/15

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V 146	Continued From page 6 create an additional barrier from potential cross contamination. Observation during the dressing change, noted individuals passing in and out of the unit in close proximity to Patient #5 while the CVC exit site was exposed at the time of the dressing change. Per the Infection Prevention Policy: Hemodialysis Out-patient and In-patient Care Sites released July 2013 states: "Purpose: To prevent the transmission of infection within the dialysis setting....Multiple factors contribute to this problem including the fact that ESRD patients are more susceptible to infection because of the process inherent in HD treatment which includes the need for long-term vascular access, including central-line use. These patients also have multiple and frequent exposures to the healthcare environment and other patients which confers multiple opportunities to acquire infection." "Policy Statement: Preventing transmission among chronic hemodialysis patients of blood borne viruses and pathogenic bacteria from both recognized and unrecognized sources of infection requires implementation of a comprehensive infection prevention program." Although the dialysis department has developed a comprehensive infection prevention program, staff at the satellite unit failed to maintain strict adherence to aseptic technique during the above mentioned procedures.	V 146			
V 176	494.40(a) H2O PURITY-ANSI/AAMI RD52:2004 The facility must be able to demonstrate the following: Water and equipment used for dialysis meets the water and dialysate quality standards and	V 176		SEE ATTACHED PLAN OF CORRECTION 9/30/15	

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V 176	<p>Continued From page 7</p> <p>equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, "Dialysate for hemodialysis," ANSI/AAMI RD52:2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552 (a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 75000 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795.</p> <p>This STANDARD is not met as evidenced by: Based on observation, staff interview and record review the facility failed to assure that all chemical test strips used to analyze the presence of chlorine/chloramine levels in HD (hemodialysis) machines following bleach disinfection of the machines, were stored in a manner that would maintain the efficacy of the strips to assure accurate readings. Findings include:</p> <p>Per observation on the morning of 8/4/15, there was an undated opened bottle of Watercheck 2 chlorine/chloramine test strips located on a shelf in the water room. Per review the manufacturer's directions for storage of the Watercheck 2 strips, which, per the Dialysis Site Supervisor was used as the unit's policy for storing the strips, directed; "use within three months after opening." Staff</p>	V 176	<p>SEE ATTACHED PLAN OF CORRECTION</p>	9/30/15

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V 176	Continued From page 8 member #5 stated, at the time of observation, that the chemical analysis strips were used to test for, and assure safe levels of, chlorine in HD machines following chemical disinfection of the internal components of the machines with bleach. S/he stated the bottle should have been marked with the date it was opened, and discarded 90 days after opening. The staff member confirmed there was no date on the bottle and therefore no way to determine how long it had been opened or when to discard the strips.	V 176		
V 542	494.90(a) POC-IDT DEVELOPS PLAN OF CARE The interdisciplinary team must develop a plan of care for each patient. This STANDARD is not met as evidenced by: Based on observation, interview and record review the interdisciplinary team failed to address the individual needs for maintaining CVC site for 1 applicable patient with a known history of hypersensitivity and inflammatory process secondary to CVC dressing supplies. (Patient #5) Findings include: 1. Per record review, Patient #5 was hospitalized from 7/1/15 to 7/15/15 with sepsis after developing a significant central line bloodstream infection (CLBSI). The infected CVC was removed and a eventually a new hemodialysis CVC was inserted prior to discharge from the hospital and dialysis treatment was resumed at the satellite. Prior to hospitalization, Patient #5 was experiencing an inflammatory reaction at the exit site of the previous CVC. With resumption of care at the satellite unit a nursing progress note dated 7/31/15 states: "S/S	V 542	SEE ATTACHED PLAN OF CORRECT	9/2/15

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V 542 Continued From page 9
(signs & symptoms) infection: No, however site is red, no drainage, cleansed with Betadine, ABX (antibiotic) ung (ointment) & DSD (dried sterile dressing). On 8/3/15 a nursing progress note states: " S/S - no, however, site is red, no drainage, cleaned with chloraprep, abx & DSD applied." Per interview on 8/5/15 at 2:55 PM the Dialysis Unit Supervisor confirmed Patient #5 has had a history of hypersensitivity to dressing supplies and the antiseptic preparations used to clean the CVC insertion site and the surrounding skin resulting in inflammatory process, skin breakdown and potential opportunity for site infection. Despite Patient #5's significant skin sensitivity and recent history of CLBSI, a plan of care had not been developed to identify specific skin products which may not create a inflammatory process from reoccurring and to determine if the antibiotic ointment was creating further skin irritation at the CVC insertion site. As a result, there was a lack of consistency among the staff who were changing the CVC dressing. In addition, the care plan failed to address the skin integrity issues nor did the interdisciplinary team assure the most appropriate products were utilized to meet the individual needs for Patient #5.

V 542

SEE ATTACHED PLAN OF CORRECTIVE

9/30/15

PLAN OF CORRECTION

V 000 INITIAL COMMENTS

An unannounced on-site re-certification survey was conducted by the Division of Licensing and Protection from 8/3/15 - 8/5/15 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 117 494.30(a)(1)(i) IC-CLEAN/DIRTY; MED PREP AREA; NO COMMON CARTS

Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that were used equipment or blood samples are handled.

When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.

Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.

This STANDARD is not met as evidenced by: Based on observation and staff interview, the dialysis unit failed to assure prepared packets of supplies used for initiation of fistula and eve (central venous catheter) treatments were stored in a clean and sanitary manner. Findings include:

During a tour on 8/4/15 at 10:55 AM of locations where unused supplies and equipment is stored for dialysis treatment, a large closet in a hallway was identified by the Unit Secretary to be the main location for supply storage. Upon observation, multiple prepared supply packets prepared by staff and containing syringes, gauze, alcohol wipes and other supplies used to clean and disinfect the access sites and/or tubing in both the initiation and discontinuation of dialysis treatment were piled in open boxes and plastic containers surrounded by boxes, and other stocked items. As a result, the prepared packets remained exposed and susceptible to possible contamination. At 11:05 AM the Dialysis Site Supervisor and the Nurse Manager for Renal Services confirmed the packets should not have been stored in the hallway closet acknowledging cabinets located in front of the nurse's station are specifically designated for the safe and sanitary storage for the prepared packets to maximize the protection of the supplies from cross contamination.

Action Plan

- Supplies were separated and enclosed in covered containers. The Dialysis Site Supervisor reinforced practice expectations with staff, as outlined in University of Vermont Medical Center (UVMC) Policy INFC00016 Infection Prevention Practices – Cleanliness of the Environment and Equipment at the 9/1/2015 meeting. Topics reviewed were separation of clean and dirty, inclusive of storing of care packs/similar items in covered clean containers. Each staff member appropriate to their role will be required to read, acknowledge and sign off on their

THE
University of Vermont
MEDICAL CENTER

understanding. The staff meetings and acknowledgement will be completed at all the UVMMC dialysis units effective 9/30/15.

- General Infection Prevention unit orientation will be reviewed and updated by the Dialysis Director and Manager in collaboration with the Manager of Infection Prevention relative to the appropriate infection prevention practices. This will be completed effective 9/30/15.
- The Infection Prevention Manager in collaboration with the Renal Dialysis Manager, created a Dialysis Infection Prevention Monitoring Checklist to include monitoring elements for practice consistent with the UVMMC Policy: INFC00016 Infection Prevention Practices– Cleanliness of the Environment and Equipment. The Renal Infection Prevention Advocates will monitor compliance monthly, effective 10/1/2015, using the Dialysis Specific Infection Prevention Checklist and provide performance feedback to the Renal Leadership for follow-up action as appropriate. Data will be shared at the unit based Quality Assurance Committee and the overall Quality Assurance Committee. In addition, the performance data will be shared by the Dialysis Director and Manager at the organization wide Standards of Operation Committee, chaired by the Chief Medical Officer.

POC
approved for
V-117
Bonnie Howe RN
9/22/15

V 122 494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL

*[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-]*

(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

This STANDARD is not met as evidenced by:

Based on observation and interview, facility staff failed to follow standard infection control precautions by not adequately cleaning and disinfecting contaminated surfaces of two dialysis stations following discontinuation of dialysis patient treatments and prior to the arrival of the next scheduled patients.

(Patient #13)

Findings include:

1) Per observation on 8/3/15 at 10:45 AM of the cleaning and disinfection of dialysis Station #9 between the first and second patient dialysis treatment sessions, Staff member #4 failed to fully recline/extend the dialysis chair to assure all surfaces were effectively wiped with disinfectant prior to the next scheduled patient was to utilize the chair during dialysis treatment.

2) Per observation of the cleaning and disinfection of Station #2 on 8/3/15 at 3:15 PM, 1 Staff #4 did not fully recline the dialysis chair and wipe all visible surfaces with a disinfectant after Patient #13 vacated the chair and before the next scheduled patient arrived. Staff #4 confirmed on 8/3/15 at 3:15 that she/he did not fully extend the dialysis chair and wipe all visible surfaces with a disinfectant. Surveyor brought this to Staff #4's attention and the chair was fully reclined and disinfected before the next scheduled patient arrived.

In addition, the facility Infection Prevention Policy:

Hemodialysis Out-patient and In-patient Care Sites date released July 2013 states "After each patient treatment, after patient has been discharged from the station, clean environmental surfaces at the dialysis station, including the surfaces of the dialysis machine, including containers associated with the prime waste".

3) Per observation of the cleaning and disinfection of Station #2 on 8/3/15 at 3:05 PM following discontinuation of Patient #13's dialysis treatment, Staff #4 placed contaminated blood lines on the dialysis machine in such a manner that the bloodlines touched the floor in front of the machine. Staff #4 was observed walking in this area, walking away from the station, and returning to the station. Staff #4 confirmed that contaminated blood lines were touching the floor and that she/he walked in this area, walked away, and returned. The floor was disinfected after the surveyor brought it to the attention of Staff #4 and prior to arrival of the next dialysis scheduled patient.

Action Plan

- The Dialysis Site Supervisor communicated appropriate practice for cleaning dialysis stations between patients in accordance with the Dialysis Station Routine Checklist, including reinforcing the requirement of fully extending the dialysis chair and cleaning all visible surfaces at the 9/1/2015 staff meeting. Each staff member appropriate to their role will be required to read, acknowledge and sign off on their understanding. In addition, this content will be added to

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the dialysis new employee orientation as appropriate to the role. The staff meetings and acknowledgement will be completed at the UVMMC dialysis units effective 9/30/15.

- Each existing dialysis employee as appropriate to their role will be required to perform a dialysis station disinfection return demonstration, which will be observed by the Dialysis Site Supervisor and/or Infection Prevention Advocate as of 9/30/2015.
- The Infection Prevention Manager in collaboration with the Renal Dialysis Manager, created a Dialysis Infection Prevention Monitoring Checklist which included dialysis station disinfection audit elements. The Renal Infection Prevention Advocates will monitor for compliance on a monthly basis, effective 10/1/2015, using the Dialysis Specific Infection Prevention Checklist. The advocates will provide performance feedback individually and to the Renal Leadership for follow-up action as appropriate. Data will be shared at the unit based Quality Assurance Committee and at the overall Quality Assurance Committee. In addition, the performance data will be shared by the Dialysis Director and Manager at the organization wide Standards of Operation Committee, chaired by the Chief Medical Officer.

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V 146 494.30(c)(2) IC-CATHETERS:GENERAL

(2)The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 1 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, IMD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For Refer to Tag -A- 0286, 0405 & 5001 information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html

This STANDARD is not met as evidenced by:

Based upon observation, interview and record review, facility staff failed to maintain strict adherence to the organizational policy when performing hemodialysis vascular access care of a central venous catheter (CVC) during a dressing change, initiation, and discontinuation of treatment for two patients and failed to maintain an environment free from the potential for cross contamination for one patient. (Patients #3 & #5)

Findings include:

Per review the facility policy, Hemodialysis Vascular Access: Central Venous Catheter (CVC), Care and Maintenance procedure for I de-accessing CVC, dated 5/14/14, states: "Prior to bloodline disconnection, the technician or RN [registered nurse] will don gown and mask, perform hand hygiene, don gloves, and place a chux under the catheter/bloodline junction." The policy also states the RN will "Scrub each extension tubing and clamp, and junction of bloodline and catheter with alcohol swabs, and hold the extensions above the chux with an alcohol swab, while placing the 4 x 3 under the extension/bloodline junction."

1. Based upon observation of a patient with a central venous catheter (CVC) discontinuing dialysis treatment on 8/3/15 at 1:45 PM, Staff #1 failed to place a chux or other clean field under Patient #3's CVC bloodline junctions prior to cleaning the catheter extensions, tubing, clamp, and bloodline junction with alcohol swabs. In addition, after Staff #1 cleaned the extensions, tubing, clamp, and bloodline junctions s/he wrapped the extensions with a gauze pad without a clean field being present underneath. Staff #1 confirmed on 8/3/15 at 1:50 PM that she/he did not place a clean field under the CVC bloodline junctions prior to cleaning and wrapping the extensions with a gauze pad.

2. Per record review, Patient #5 was hospitalized from 7/1/15 to 7/15/15 with sepsis after developing a significant central line bloodstream infection (CLBSI). The infected CVC was removed and eventually a new hemodialysis CVC was inserted prior to discharge from the hospital and dialysis treatment was resumed at the satellite unit. Per observation of Patient #5's CVC dressing change on 8/5/15 at 11:05 AM, Staff member #10 failed to maintain strict adherence to the dialysis department infection control policy. Staff member #10 was observed removing the old CVC dressing, cleaning the CVC insertion site and catheter and applied a new dressing to the CVC site with only a 4 x3 gauze pad under the catheter extensions without the use of a chux pad, as per policy, which would have provided an additional clean field barrier prior to the initiation of the dressing change and accessing the CVC for dialysis. It was also noted Patient #5 was receiving treatment at Station

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#3 which is located directly beside the entrance/exit to the Satellite unit, a high traffic area. Individuals were observed passing in close proximity of Patient #5 while s/he sat in the dialysis chair during the dressing change procedure. At the time of the CVC dressing change, Staff member #10 failed to draw the privacy curtain around Station #3 to create an additional barrier from potential cross contamination. Observation during the dressing change, noted individuals passing in and out of the unit in close proximity to Patient #5 while the CVC exit site was exposed at the time of the dressing change.

Per the Infection Prevention Policy: Hemodialysis Out-patient and In-patient Care Sites released July 2013 states: "Purpose: To prevent the transmission of infection within the dialysis settingMultiple factors contribute to this problem including the fact that ESRD patients are more susceptible to infection because of the process inherent in HD treatment which includes the need for long-term vascular access, including central-line use. These patients also have multiple and frequent exposures to the healthcare environment and other patients which confers multiple opportunities to acquire infection." "Policy Statement: Preventing transmission among chronic hemodialysis patients of blood borne viruses and pathogenic bacteria from both recognized and unrecognized sources of infection requires implementation of a comprehensive infection prevention program." Although the dialysis department has developed a comprehensive infection prevention program, staff at the satellite unit failed to maintain strict adherence to aseptic technique during the above mentioned procedures.

Action Plan

- The Dialysis Site Supervisor reeducated the applicable staff on the practices outlined in UVMHC Hemodialysis Vascular Access; Central Venous Catheter Care and Maintenance Policy at the 9/1/2015 staff meeting. Each applicable staff member will be required to read, acknowledge and sign off on their understanding. The staff meetings and acknowledgements will be completed at the UVMHC dialysis units effective 9/30/15.
- Each applicable employee will be required to perform a return demonstration in accordance with the referenced policy observed by the Dialysis Site Supervisor(s) and/or Infection Prevention Advocate as of 9/30/2015.
- The Infection Prevention Manager in collaboration with the Renal Dialysis Manager, created a Dialysis Infection Prevention Monitoring Checklist to include monitoring elements for practice consistent referenced infection prevention practices in regards to the referenced policy. The Renal Infection Prevention Advocates will monitor compliance monthly, effective 10/1/2015, using the checklist and provide performance feedback individually, and to the Renal Leadership for follow-up action as appropriate. Data will be shared at the unit based Quality Assurance Committee and the overall Quality Assurance Committee. In addition, the performance data will be shared globally by the Dialysis Director and Manager at the organization wide Standards of Operation Committee, chaired by the Chief Medical Officer.

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9/22/15*

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V 176 494.40(a) H2O PURITY-ANSI/AAMI RD52:2004

The facility must be able to demonstrate the following:

Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, "Dialysate for hemodialysis, ANSI/AAMI RD52:2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552 (a) and CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 75000 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.

Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795.

This STANDARD is not met as evidenced by: Based on observation, staff interview and record review the facility failed to assure that all chemical test strips used to analyze the presence of chlorine/chloramine levels in HD (hemodialysis) machines following bleach disinfection of the machines, were stored in a manner that would maintain the efficacy of the strips to assure accurate readings. Findings include:

Per observation on the morning of 8/4/15, there was an undated opened bottle of Watercheck 2 chlorine/chloramine test strips located on a shelf I in the water room. Per review the manufacturer's directions for storage of the Watercheck 2 strips, which, per the Dialysis Site Supervisor was used as the unit's policy for storing the strips, directed; "use within three months after opening." Staff member #5 stated, at the time of observation, that the chemical analysis strips were used to test for, and assure safe levels of, chlorine in HD I machines following chemical disinfection of the internal components of the machines with bleach. S/he stated the bottle should have been marked with the date it was opened, and discarded 90 days after opening. The staff member confirmed there was no date on the bottle and therefore no way to determine how long it had been opened or when to discard the strips.

Action Plan

- The Dialysis Site Supervisor reeducated the applicable staff on the practice of labeling test strip bottles with outdates in accordance with the manufacturer's guidelines at the 9/1/2015 staff meeting. Each applicable staff member will be required to read, acknowledge and sign off on their understanding. Staff meetings and acknowledgements will be completed at all UVMMC dialysis units effective 9/30/15.
- The Infection Prevention Manager in collaboration with the Renal Dialysis Manager, created a Dialysis Infection Prevention Monitoring Checklist to include monitoring elements for practice consistent with appropriate test strip labeling. The Renal Infection Prevention Advocates will monitor compliance monthly, effective 10/1/2015, using the checklist and provide performance feedback individually, and to the Renal Leadership for follow-up action as appropriate. Data will be shared at the unit based Quality Assurance Committee and the overall Quality Assurance Committee. In addition, the performance data will be shared by the Dialysis Director and

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Manager at the organization wide Standards of Operation Committee, chaired by the Chief Medical Officer.

V 542, 494.90(a) POC-IDT DEVELOPS PLAN OF CARE:

The interdisciplinary team must develop a plan of care for each patient.

This STANDARD is not met as evidenced by: Based on observation, interview and record review the interdisciplinary team failed to address the individual needs for maintaining CVC site for applicable patient with a known history of hypersensitivity and inflammatory process secondary to CVC dressing supplies. (Patient #5)

Findings include:

Per record review, Patient #5 was hospitalized from 7/1/15 to 7/15/15 with sepsis after developing a significant central line bloodstream infection (CLBSI). The infected CVC was removed and eventually a new hemodialysis CVC was inserted prior to discharge from the hospital and dialysis treatment was resumed at the satellite. Prior to hospitalization, Patient #5 was experiencing an inflammatory reaction at the exit site of the previous CVC.

With resumption of care at the satellite unit a nursing progress note dated 7/31/15 states: "S/S: (signs & symptoms) infection: No, however site is red, no drainage, cleansed with Betadine, ABX (antibiotic) ung (ointment) & DSD (dried sterile dressing). On 8/3/15 a nursing progress note states: " S/S - no, however, site is red, no drainage, cleaned with chloraprep, abx & DSD applied." Per interview on 8/5/15 at 2:55 PM the Dialysis Unit Supervisor confirmed Patient #5 has had a history of hypersensitivity to dressing supplies and the antiseptic preparations used to clean the CVC insertion site and the surrounding skin resulting in inflammatory process, skin breakdown and potential opportunity for site infection. Despite Patient #5's significant skin sensitivity and recent history of CLBSI, a plan of care had not been developed to identify specific skin products which may not create a inflammatory process from reoccurring and to determine if the antibiotic ointment was creating further skin irritation at the CVC insertion site. As a result, there was a lack of consistency among the staff who were changing the CVC dressing. In addition, the care plan failed to address the skin integrity issues nor did the interdisciplinary team assure the most appropriate products were utilized to meet the individual needs for Patient #5.

Action Plan

- The Dialysis Site Supervisor reeducated the applicable staff on the practice of dialysis access plan of care documentation requirements in CyberRen at the 9/1/2015 staff meeting. Each applicable staff member will be required to read, acknowledge and sign off on their understanding. Staff meetings and acknowledgements will be completed at all UVMMC dialysis units effective 9/30/15.
- The patient's yearly "Plan of Care" will address the "current" prescription for site care (dressing type, skin cleanser, etc.), taking into account any special considerations for increased risk potentials such as infection sources and skin sensitivity as applicable.
- On a monthly basis and as needed, the Primary Nurse will document the dialysis access site assessment and any changes to the plan of care around site care in the "Access Assessment Screen" in CyberRen. Site care instructions will also be documented and kept current in the "Alert" screen in CyberRen. The alert Screen is reviewed by the RN and CCHT during the pre-

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dialysis “Golden Moment” prior to all dialysis sessions.

- The dialysis access site will be assessed at each dialysis treatment and this assessment will be documented in the daily progress note in CyberRen. If during this assessment it is decided that a change to site care prescription is warranted, the CyberRen “Alert Screen” will be updated with the site care changes.
- The Dialysis Site Supervisor or Vascular Access Coordinator at each unit will monitor for plan completeness on a monthly basis. Data will be shared at the unit based Quality Assurance Committee and the overall Quality Assurance Committee. In addition, the performance data will be shared by the Dialysis Director and Manager at the organization wide Standards of Operation Committee, chaired by the Chief Medical Officer.

*POC approved
for V-542
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9/22/15*